

THE PLACEBO EFFECT IN CLINICAL PRACTICE

Release Date: October 26, 2001

RFA: RFA-AT-02-001

National Center for Complementary and Alternative Medicine

(<http://nccam.nih.gov>)

John E. Fogarty International Center

(<http://www.nih.gov/fic>)

National Heart, Lung, and Blood Institute

(<http://www.nhlbi.nih.gov>)

National Institute on Aging

(<http://www.nih.gov/nia>)

National Institute on Alcohol Abuse and Alcoholism

(<http://www.niaaa.nih.gov>)

National Institute of Allergy and Infectious Diseases

(<http://www.niaid.nih.gov>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

(<http://www.niams.nih.gov>)

National Institute of Dental and Craniofacial Research

(<http://www.nidr.nih.gov>)

National Institute of Diabetes and Digestive and Kidney Diseases

(<http://www.niddk.nih.gov>)

National Institute of Mental Health

(<http://www.nimh.nih.gov>)

Letter of Intent Receipt Date: March 1, 2002

Application Receipt Date: April 11, 2002

THIS RFA USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. MODULAR INSTRUCTIONS MUST BE USED FOR RESEARCH GRANT APPLICATIONS REQUESTING LESS THAN \$250,000 PER YEAR IN ALL YEARS. 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 proposed initiative is expected to stimulate investigator-initiated research investigations on how placebos and placebo effects impact on clinical practice. An important goal is to understand what factors are necessary to elicit a placebo effect in clinical practice so that the benefits of the therapeutic intervention can be enhanced to improve health and promote wellness.

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 Request for Applications (RFA), "The Placebo Effect in Clinical Practice" is related to one or more of the priority areas. Potential applicants may obtain "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, 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.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01) and the developmental/exploratory grant (R21) award mechanisms. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to this RFA may not exceed 4 years for R01 grants and 2 years for R21 grants. At this time, it is not known if this RFA will be reissued. Therefore, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The earliest anticipated award date is September 2002.

FUNDS AVAILABLE

NCCAM intends to commit approximately 1.13 million dollars in total costs in FY 2002 and/or FY 2003 to fund 4 to 6 new grants. In addition, FIC, NIA, NHLBI, NIAMS, and NIDCR intend to

contribute a total of approximately 1.06 million dollars in FY 2002 and/or FY 2003 to fund additional grants applications that respond to this RFA. Finally, NIAAA, NIAID, NIDDK, and NIMH may provide support to other meritorious applications that fit their program objectives.

R21 grant applicants may request a project period of up to two years with a total direct cost per year of \$125,000. R01 grant applicants may request a project period of up to 4 years. A direct cost budget limit is not specified for R01 grants.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of each award will also vary. Although the financial plans of the NCCAM and other NIH Institute/Centers provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

RESEARCH OBJECTIVES

Background

The benefits of therapeutic interventions in clinical practice are often enhanced by placebo effects. Placebo effects can be defined as the positive physiological or psychological changes associated with the use of inert medications, sham procedures, or therapeutic symbols within a healthcare encounter. Placebos can also be active substances or real procedures that produce unexpected beneficial effects. For example, antibiotics may be considered placebos when prescribed for viral respiratory illnesses that are not expected to respond to antibiotic action. Placebo effects may also be viewed as a subset of a larger group of mind-brain-body effects such as the psycho-physiological effects of religious beliefs and devotional practices, meditation, faith-based healing, hypnosis, and the effects of cultural and social economic systems on the prevalence and severity of specific diseases. These effects have been scientifically documented by an increasing body of research. Mind-brain-body effects, including placebo effects, are not fully appreciated in contemporary medicine. This may be explained, in part, as a legacy of the Cartesian model that envisions the mind as being something discrete from brain and body, and by the powerful reductionist approach of the current biomedical model. This reductionist model characterizes conventional medicine in that healthcare practitioners are trained to focus primarily on finding and eliminating physiologically demonstrable pathology. Placebos were assigned a negative connotation when the term was first coined in the early 19th century to describe a medicine "adapted more to please than benefit the patient." With the scientific transformation of medicine, particularly since the Second World War, this pejorative connotation was reinforced as the randomized double-blind placebo-controlled clinical trial emerged as the "gold standard"

allowing investigators to subtract the "noise" of placebo effects from the actual therapeutic responses to newly developed drugs and medical/surgical procedures. Yet, prior to the development of the armamentarium of contemporary drugs and medical/surgical techniques in the second half of the last century, medicine included what we now call placebos as part of clinical practice. And with such treatments, patients sometimes felt better and even showed improvements in health status.

Now we are witnessing a further evolution in how placebo and other related effects are perceived, facilitated by a substantial body of research that provides compelling evidence of mind-brain-body interactions at the organismal, cellular, and molecular levels. At a recent meeting convened by the John D. & Catherine T. MacArthur Foundation, Network on Mind-Body Interactions and NIH, scientists reported on the biology of social interactions, the neurobiology of emotions, and molecular neuroendocrine and neural factors in inflammatory and infectious disease. Research presented at this meeting highlighted the many ways through which the mind can influence the brain and body. Another recent meeting, "The Science of the Placebo: Towards an Interdisciplinary Research Agenda" outlined a multilayer model in which placebo effects operate through psychosocial mechanisms such as belief, conditioning, expectancy, and meaning response. These mechanisms, in turn, evoke physiological responses that may affect biological pathways in neurological, immune, endocrine, cardiovascular, gastrointestinal, and/or other organ systems to relieve disease symptoms. The purpose of this meeting was to develop an interdisciplinary research agenda on the science and ethics of the placebo, based on a scholarly assessment of the field. The participants developed 3 sets of recommendations: (1) to further elucidate the basis of placebo effects, (2) to investigate the use of placebo effects in clinical practice; and (3) to study the placebo effects as they relate to methodology and ethics of clinical trials.

This RFA is informed by the two recent NIH meetings described above and focuses on the use of placebo in clinical practice to improve health. A companion RFA pertains to the elucidation of the underlying biological mechanisms of placebo effects. Further understanding of the placebo effect also has important implications for clinical trials. To determine the efficacy of pharmacological, procedural, or behavioral interventions, clinical trials methodology must be designed to account for placebo effects. In particular, it is important to distinguish placebo effects from measurement and methodological factors as well as effects of the actual treatment being tested. These other factors may be biological, behavioral, or methodological. They include the natural history of the disease, investigator and patient biases, the reliability of measurements taken, regression to the mean, reactivity of the measurement, practitioner and observer bias, spontaneous remissions, and confounded therapeutic procedures. Unfortunately, these measurement and methodological factors are sometimes grouped inappropriately with placebo effects. They can best be distinguished from placebo effects when a no treatment control is included in the study design.

Complicating things further, the relationship between placebo and treatment effects may not be purely additive, but rather dynamically interactive. Furthermore, the question of whether the use of placebo in clinical trials under some circumstances is even ethical has engendered a lively debate centered around the recently revised Declaration of Helsinki. Participants in the “Science of the Placebo” meeting discussed a number of methodological and ethical issues that needed to be addressed related to the use of placebo controls in clinical trials. Another solicitation from NIDDK will call for applications to address these issues related to clinical trials.

Goals and Scope

Understanding how to enhance the therapeutic benefits of placebo effect in clinical practice has the potential to significantly improve healthcare. The objectives of this initiative are to encourage interdisciplinary studies involving social and behavioral sciences as well as other appropriate scientific disciplines to reveal those factors that are important for eliciting placebo effects in a clinical practice setting. Innovative research including, but not limited to, the following is encouraged:

- o Systematic studies to determine what psychosocial factors in the patient/healthcare practitioner relationship and in the healthcare environment are important for eliciting placebo effect, such as shared beliefs, hope, expectancy, meaning response, and conditioning.
- o Studies on various tools that may be used to elicit placebo effect.
- o Investigations into the role played by cultural beliefs and social economic systems in eliciting placebo effect in clinical practice.
- o Investigations of ethical questions of placebo use in clinical practice.
- o Research on how different types of healthcare practitioners can maximize the placebo effect, thus potentiating the healing effects of therapeutic interventions in clinical practice. For example, are complementary and alternative medicine (CAM) practitioners, who generally take a more holistic approach in clinical practice, better at eliciting placebo effects to enhance actual therapeutic interventions than conventional practitioners, who may take a more reductionist approach?
- o Studies of barriers to eliciting placebo effects.
- o Studies investigating the specificity, timing, and size of placebo effects in relation to different disease conditions, medical interventions and social context.

Several NIH Institutes and Centers have joined NCCAM to support this initiative. Examples of specific topics of interest to individual NIH Institutes/Centers are listed under INQUIRIES in this announcement along with contact information for each participating NIH Institute and Center.

SPECIAL REQUIREMENTS

o Monitoring Plan and Data Safety and Monitoring Board:

Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

NCCAM requires that all masked clinical trials, regardless of size, establish an independent data and safety monitoring board (DSMB). Funds should be budgeted for these activities. They should not duplicate internal review and monitoring systems that are already in place at the institution.

o Adverse Events Reporting:

All studies should have a structured adverse event determination, monitoring and reporting system, including standardized forms and protocols for referring and/or treating subjects experiencing adverse events. The proposed schedule for reporting adverse events to the DSMB, the NCCAM Program Officer and/or the FDA should be described.

NIA Requirements for Human Intervention Studies

NIA may request specific information related to human intervention studies prior to award. Information describing NIA requirements, "Implementation of Policies for Human Intervention Studies," are available at: <http://www.nih.gov/nia/funding/policy/humint.htm>.

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 biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are 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 research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>); a complete copy of the updated Guidelines is available at

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm. The revisions relate to NIH-defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to 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) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of 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 Inclusion of Children as Participants in Research Involving Human Subjects," published in the NIH Guide for Grants and Contracts, March 6, 1998, and available at:

<http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators also may 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>.

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. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

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 RFA 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.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent to Nancy J. Pearson, Ph.D. at the address listed under INQUIRIES, below, by March 1, 2002.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> must be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

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.

SPECIFIC INSTRUCTIONS FOR R21 GRANT APPLICATIONS

Applicants who anticipate submitting an R21 grant application should review the NCCAM website at <http://nccam.nih.gov/research/instructions/r21/index.htm> for specific information about this mechanism.

The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

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)

Applications must be received by the application receipt date listed in the heading of the RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA 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 substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and for responsiveness to this RFA by NCCAM. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national councils or advisory boards of the participating NIH institutes and centers.

Review Criteria

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. 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 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.

(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 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 methods? 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 proposed 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?

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

- o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

- o The reasonableness of the proposed budget and duration in relation to the proposed research.

- o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

For exploratory/developmental (R21) grant applications, preliminary data as evidence of feasibility of the project are not required, since this grant award mechanism is designed to support exploratory, innovative ideas. However, the applicant does have the responsibility for developing a sound research plan approach, including appropriate statistical analyses and sample size calculations where appropriate. Innovation of the project and potential significance of the proposed research will be major considerations in the evaluation of this mechanism.

SCHEDULE

Letter of Intent Receipt Date: March 1, 2002
Application Receipt Date: April 11, 2002
Peer Review Date: June/July 2002
Council Review: September/October 2002
Earliest Anticipated Start Date: September 2002

AWARD CRITERIA

Criteria that will be used to make award decisions include:

- o scientific merit (as determined by peer review)
- o availability of funds
- o programmatic priorities.

INQUIRIES

Inquiries concerning this RFA are encouraged. Examples of topics of interest to specific NIH Institutes/Centers are listed below. The opportunity to clarify any issues or answer questions from potential applicants is welcome.

Direct general inquiries to:

Nancy J. Pearson, Ph.D.
Program Officer
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd.
Democracy 2, Room 106, MSC 5475
Bethesda, MD 20892

Telephone: (301) 594-0519
FAX: (301) 480-3621
Email: pearsonn@mail.nih.gov

Direct inquiries regarding fiscal matters to:

Victoria Carper
Grants Management Officer
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd/Rm 106/MSC 5475
Bethesda, MD 20892
Telephone: (301) 594-9102
FAX: (301) 480-3621
Email: carperv@mail.nih.gov

Direct inquiries regarding specific programmatic issues to the staff of the appropriate Institute or Center:

JOHN E. FOGARTY INTERNATIONAL CENTER

FIC is interested in research on placebo and placebo effects that involve international sites or international collaborations.

Aron Primack, MD, MA
Fogarty International Center
National Institutes of Health
Bldg 31, Room B2C39
31 Center Drive
Bethesda, MD 20892-2220
Telephone: (301) 496-4596
Fax: (301) 402-0779
Email: aron_primack@nih.gov

NATIONAL CANCER INSTITUTE

While not formally participating in this RFA, NCI is interested in research relevant to the effect of the placebo in clinical practice. This research may apply to cancer prevention, early detection, treatment or survivorship, and may involve pre-intervention or intervention research applications.

Michael Stefanek, Ph.D.
Basic Biobehavioral Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Boulevard/EPN 4066
Bethesda, MD 20892
Telephone: (301) 496-8776
Email: ms496r@nih.gov

THE NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
NCCAM is interested in research on how placebo effects can enhance the use, efficacy, or safety of alternative and complementary therapies in clinical practice.

Nancy J. Pearson, Ph.D.
Program Officer
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd.
Democracy 2, Room 106, MSC 5475
Bethesda, MD 20892
Telephone: (301) 594-0519
FAX: (301) 480-3621
Email: pearsonn@mail.nih.gov

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NHLBI is interested in studies that measure and describe the psychological and emotional (attitudes, expectancies, hope, affective states), social (social support; patient-provider communication and interaction) and contextual (cultural belief systems, socioeconomic status, features of the health care setting, community norms) factors that elicit placebo effects in clinical practice settings. Placebos have been found to influence physiologic outcomes and responses to treatment for many different diseases. NHLBI has a particular interest in studies of patients who are at risk for or have existing cardiovascular, lung, blood and sleep diseases or disorders in order to a better understanding of how placebo responses operate within clinical care settings in order to design better interventions to improve treatment outcomes.

Susan M. Czajkowski, Ph.D.
Behavioral Medicine Scientific Research Group

Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Rockledge 2, Room 8114
6701 Rockledge Drive
Bethesda, MD 20892
Telephone: (301) 435-0406
FAX: (301) 480-1773
E-mail: CzajkowS@nih.gov

NATIONAL INSTITUTE ON AGING

NIA is interested in research examining the extent to which susceptibility to placebo effects changes between midlife and old age as well as factors contributing to any such changes.

Daniel B. Berch, Ph.D.
Chief, Section on Cognitive Aging
Individual Behavioral Processes Branch
Behavioral and Social Research Program
National Institute on Aging, NIH
7201 Wisconsin Avenue, Suite 533
Bethesda, MD 20892-9205
Telephone: (301) 594-5942
Fax: (301) 402-0051
E-mail: Daniel_Berch@nih.gov

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

The National Institute on Alcohol Abuse and Alcoholism is interested in research on the effectiveness of placebos in clinical treatment of alcohol dependence and abuse. Meritorious applications received under this RFA will be considered for funding by NIAAA based on funding availability.

Charlene E. LeFauve, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Willco Bldg., Suite 505
6000 Executive Blvd.
Bethesda, MD 20892-7003 (Fed.Ex. Zip: Rockville, MD 20852)

Telephone: (301) 402-9401

Fax: (301) 443-8774

E-mail: clefauve@nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NIAID is interested in applications that study the effect of placebos on immune-mediated diseases, such as Asthma and Allergic Diseases, Autoimmune Diseases and Transplant rejection, and infectious diseases, including HIV/AIDS.

Stephen M. Rose, Ph.D.

Director, Office of Clinical Applications

Acting Chief, Transplantation Immunobiology Branch

Division of Allergy, Immunology and Transplantation

NIAID, NIH

6700-B Rockledge Drive, Room 5133

Bethesda, MD 20892-7640

Telephone: (301) 496-5598

Fax: (301) 402-2571 FAX

Email: srose@niaid.nih.gov

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

NIAMS is interested in research on the use of effectiveness of placebos in managing arthritis, fibromyalgia, and other rheumatic diseases, muscle diseases, musculoskeletal disorders, bone diseases, and skin diseases.

Deborah N. Ader, Ph.D.

Director, Behavioral and Prevention Research Program

NIAMS

45 Center Dr., Bldg. 45, Rm. 5A19H

Bethesda, MD 20892-6500

Telephone: (301) 594-5032

FAX: (301) 480-4543 (fax)

Email: aderd@mail.nih.gov

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

NIDCR encourages applications in response to this RFA for research relevant to dental or oral diseases or their treatments. This includes an interest in studies relevant to management of

acute pain associated with oral surgery or dental restorations or craniofacial conditions such as TMJ disorders or burning mouth syndrome, which commonly involve persisting pain.

Patricia S Bryant, Ph.D.

Program Director, Behavior and Health Promotion Research

Division of Population and Health Promotion Studies

National Institute of Dental and Craniofacial Research

NIDCR

45 Center Dr, Bldg 45, Rm 4AN24E

Bethesda Md 20892

Telephone: (301) 594-2095

FAX: (301) 480-8318

Email: BryantP@de34.nidr.nih.gov

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

NIDDK is interested in studying the placebo effect in clinical studies of disorders for which a treatment outcome is based solely on subjective assessment of change in symptoms. Of particular interest are studies of therapeutic treatments for diabetes and digestive and kidney diseases.

Leroy M. Nyberg, Jr., Ph.D., M.D.

Director, Urology Programs, DKUHD

National Institute of Diabetes and Digestive and Kidney Diseases

Democracy 2, Room 627

Bethesda, MD 20892-5458

Telephone: (301) 594-7717

FAX: (301) 480-3510

Email: NybergL@extra.niddk.nih.gov

NATIONAL INSTITUTE OF MENTAL HEALTH

NIMH is not committing funds to this RFA at this time. Meritorious applications for research relevant to NIMH will be considered based on funds availability and program priority.

Edgardo J. Menvielle, MD, MSHS

Medical Officer (Psychiatrist)

Child and Adolescent Treatment and Preventive Intervention Research Branch,

Division of Services and Intervention Research,

National Institute of Mental Health
6001 Executive Boulevard, Room 7149, MSC 9633
Bethesda, MD 20892
Telephone: (301) 443-3815
Fax: (301) 443-4045
Email: emenviel@mail.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.213(NCCAM); 93.989(FIC); 93.837,93.838(NHLBI); 93.866(NIA); 93.273(NIAAA); 93.855,93.856(NIAID); 93.846(NIAMS); 93.121 (NIDCR); 93.849(NIDDK); 93.242(NIMH). 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. 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 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, 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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