

Obtain Additional Information" section of this announcement.

G. Evaluation Criteria

The application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. *Background and Need (33 Points)*: Extent to which applicant demonstrates a clear understanding of the purpose and objectives of this proposed cooperative agreement and demonstrates a clear understanding of the requirements, responsibilities, interactions, problems, constraints, complexities, etc., that may be encountered in conducting the project and performing the studies.

2. *Capacity and Personnel (33 Points)*: Extent to which applicant demonstrates past experience of professional personnel in conducting studies similar to those proposed in this cooperative agreement. Extent to which applicant demonstrates it has adequate administrative personnel and support. Extent to which applicant demonstrates it has adequate scientific resources and facilities (including certified BSL-3 laboratory) to successfully conduct the activities.

3. *Objectives and Technical Approach (34 Points)*: Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and goals of this grant/cooperative agreement program and which are measurable and time-phased. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all "Recipient Activities." Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the plan is adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant describes adequate and appropriate collaboration with CDC and/or others during various phases of the project. Extent to which applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving project objectives.

4. *Budget (Not Scored)*: Extent to which applicant presents a detailed, line-item budget with a detailed narrative justification (by line-item) that

is consistent with the purpose and objectives of this cooperative agreement.

5. *Animal Subjects (Not Scored)*: Does the application adequately address the requirements of PHS Policy on Humane Care and Use of Laboratory Animals?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Progress reports (semiannual);
2. Financial Status Report (FSR), no more than 90 days after the end of the budget period; and
3. Final FSR and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-3 Animal Subjects Requirements
- AR-7 Executive Order 12372 Review
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC [ATSDR] announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "funding" then "Grants and Cooperative Agreements."

To obtain additional information, contact: Merlin Williams, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770)488-2765, E-mail address: mqw6@cdc.gov.

For program technical assistance, contact: Dr. James N. Mills, Special Pathogens Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., M/S G-14, Atlanta, Georgia 30333, Telephone: (404)639-1396.

Dated: May 11, 2000.

Henry S. Cassell, III,

Acting, Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 00111]

Development and Testing of New Medications for Treatment of Emerging Infectious Diseases; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for the development and testing of new medications for emerging infectious diseases. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Immunization and Infectious Diseases. For the conference copy of "Healthy People 2010", visit the internet site <http://www.health.gov/healthypeople>.

The purpose of this program is for the development and testing of new anti-infectious agents developed from natural products primarily for use in humans. Of particular, but not exclusive interest are anti-infective agents for parasitic diseases. Projects may include, but are not limited to a range of activities such as identifying promising agents, purifying or creating them, optimizing them for clinical use, and testing them.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying

activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$1,500,000 is available in FY 2000 to fund one award. It is expected the award will begin on or about September 1, 2000, and will be made for a 12-month budget period within a project period of up to three years. The funding estimate may change.

A continuation award within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities) and CDC will be responsible for conducting activities under 2. (CDC Activities):

1. Recipient Activities

a. Develop and implement strategies for selection of emerging infectious disease(s) that affect humans and or acquiring or developing new medications for treatment of those diseases using natural products. This includes studying the pharmacologic and biologic characteristics of natural product structures and analogs and designing molecules using computer methods for known biochemical targets.

b. Use combinatorial methods to optimize anti-infectives resulting from these approaches.

c. Develop strategies and capacity to produce adequate quantities of compound, for example, by using an automated organic synthesizer or other technology.

d. Develop and implement a systematic approach to in vitro testing of drug candidates.

e. Conduct in vivo testing of promising candidates if appropriate.

f. Develop a plan for enhancing commercial interest in promising drugs.

g. Publish or disseminate results of research.

2. CDC Activities

a. Provide technical assistance in the design and conduct of the research, as needed.

b. Perform selected laboratory tests, as requested.

c. Provide biological materials (e.g., strains, reagents, etc.) as necessary or appropriate.

d. Assist in the development of assays for evaluating pharmacokinetics of new drugs as necessary or appropriate.

e. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 double spaced pages printed on one side, with one inch margins and un-reduced font.

F. Submission and Deadline

Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit.

On or before July 1, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" Section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

1. Background and Need (15 Points)

Extent to which applicant demonstrates a clear understanding of the background, purpose, and objectives of the focus area being addressed and the relevance of disease(s) to be studied. Extent to which applicant demonstrates that the proposed project addresses the purpose. Extent to which the applicant demonstrates that the proposed program

collaborates with and does not duplicate existing rational development efforts.

2. Capacity (40 Points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) to use natural products, computer-aided drug design, and development of analogs of known drugs to develop strategies for producing adequate quantities of compound, for example, by using automated organic synthesis or other technologies for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from participating non-applicant organizations, individuals, etc., and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 Points Total)

a. Extent to which applicant describes measurable and time-phased objectives of the proposed project which are consistent with the purpose of the focus area being addressed. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all recipient activities for the specific programmatic focus area being addressed. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/ methods for conducting the proposed studies and extent to which the approach/methods are feasible, appropriate, and adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant clearly describes collaboration with others during various phases of the project. (25 points)

c. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes (a) the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation, (b) the proposed

justification when representation is limited or absent, (c) a statement as to whether the design of the study is adequate to measure differences when warranted and

(d) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (5 points)

4. Evaluation

Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives. (5 points)

5. Budget (Not Scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

7. Animal Subjects (Not Scored)

Does the application adequately address the requirements of PHS Policy on Humane Care and Use of Laboratory Animals?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. progress reports (semiannual);
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirements
- AR-7 Executive Order 12372 Review
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To obtain additional information, contact: Andrea Wooddall, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number 770-488-2749, Email address ayw3@cdc.gov

For program technical assistance, contact: Sue Binder, M.D., Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 4770 Buford Highway, N.E., Atlanta, GA 30333, Telephone number 770-488-7793, Email address scb1@cdc.gov

Dated: May 11, 2000.

Henry S. Cassell, III,

Acting, Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00118]

Mind/Body Research Program; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a grant to conduct mind/body research.

CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010" a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Disability and Secondary Conditions, and Physical Activity and Fitness. Other health objectives for the nation can ultimately be addressed through mind/body research because approaches that evoke the relaxation response may impact positively on a variety of chronic health conditions and

disabilities targeted by the 2010 objectives.

For the conference copy of "Healthy People 2010", visit the internet site: <<http://www.health.gov/healthypeople>>.

The purpose of this program is to generate knowledge through basic and clinical research about the effectiveness of a relaxation or stress reduction approach such as meditation or progressive muscle relaxation that evokes changes in psychophysiology and can, consequently, impact positively on physical and mental health. These psychophysiology outcomes, collectively labeled the relaxation response, include decreased heart rate, blood pressure, muscle tension, metabolism, breathing rate, and brain wave activity. Project objectives and activities should add to the literature, and include those that articulate the acute (changes that occur as a result of a single session) and chronic (changes that occur as a result of numerous sessions repeated over time) benefits of an approach that evokes the relaxation response. Such efforts should be highlighted by identifying and advancing knowledge about the causal mechanisms underlying the neural and systemic adaptations that trigger the relaxation response (e.g., acute transient change in systolic and diastolic blood pressure) and related chronic health outcomes (e.g., reductions in resting systolic and diastolic blood pressure in patients with hypertension). In addition, a goal of this project should be to identify determinants or correlates that assist in predicting who will initiate, maintain, and benefit from an approach that evokes the relaxation response. In this regard, identifying and understanding how important sociodemographic variables, health status and belief systems, influence use and effectiveness of an approach that evokes the relaxation response are desired study outcomes.

Numerous medical conditions, including hypertension, pain, and stress related mood disturbance, have responded favorably to treatment using approaches that evoke the relaxation response. Little is known about the processes that account for the improvements in health. This project requires that multi-disciplinary and well controlled study(ies) with healthy or clinical populations be conducted to investigate the physiological basis for treatment of modality effectiveness, as well as psychosocial attributes influencing successful treatment response.