ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
		ORAL	CHRONIC	0.002 mg/kg/day	100	Hematological.
2,6-DINITROTOLUENE	000606–20–2	ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Neurological.
4,4′-METHYLENE-BIS (2-CHLOROANILINE).	000101–14–4	ORAL	CHRONIC	0.003 mg/kg/day	3000	Hepatic.
4,6-DINITRO-O-CRESOL.	000534–52–1	ORAL	ACUTE	0.004 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.004 mg/kg/day	100	Neurological.

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Centers for Disease Control and Prevention

[Announcement Number 662]

Applied Research in Emerging Infections—Controlling the Spread of Antimicrobial Resistance in Community-Acquired Bacterial Pathogens

Introduction

The Centers for Disease Control and Prevention (CDC) is implementing a program for competitive cooperative agreement and/or research project grant applications to support applied research on emerging infections. CDC announces the availability of fiscal year (FY) 1996 funds to provide assistance for a program to conduct research on controlling the spread of antimicrobial resistance among community-acquired bacterial pathogens.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where To Obtain Additional Information.)

Authority

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

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, including State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately $250,000 is available in FY 1996 to fund one or two awards. It is expected that the awards will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Purpose

The purpose of the emerging infections extramural research program is to provide financial and technical assistance for applied research projects on emerging infections in the United States. As a component of this emerging infections extramural research program, this announcement focuses on controlling the spread of antimicrobial resistance among community-acquired bacterial respiratory pathogens.

Specifically, the purpose of this announcement is to provide assistance for the development and implementation of a program to promote judicious antimicrobial use in an outpatient population, and the evaluation of its impact on carriage or infection with community-acquired drug-resistant bacterial respiratory pathogens. If successful, such a project could serve as the scientific foundation for national efforts to change antibiotic use practices of physicians in order to decrease the spread of resistance.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A., below and CDC shall be responsible for conducting activities under B., below. In Recipient Activities below, the study of drug resistant S. pneumoniae, H. influenzae, or M. catarrhalis in a pediatric population are examples of an appropriate approach and are provided for illustration purposes. Applicants may propose studies which focus on other populations and/or pathogens which are appropriate under the Purpose section of this announcement.

A. Recipient Activities

1. Select study population. This may include selection of non-overlapping control and intervention groups of patients for participation. One example of an appropriate approach would be to enroll children from two groups of day care centers, from two small towns, or from two communities within a large metropolitan area. These groups of children would constitute discrete populations and be served by different medical care providers. They would be similar demographically, have similar utilization of medical care, and comparable baseline rates of carriage or infection with resistant pathogens.

2. Collect and analyze baseline data. For example, nasopharyngeal (NP) carriage rates for drug-resistant Streptococcus pneumoniae (DRSP) and/or β-lactamase producing Haemophilus influenzae or Moraxella catarrhalis could be measured in the two groups of children by separate NP swab surveys conducted several months before and immediately prior to the start of the intervention phase. NP surveys for the intervention and control groups would be done concurrently. Laboratory methods would include evaluating the potential for carriage of multiple populations of pneumococci, which

may have different resistance patterns, by analysis of multiple pneumococcal colonies per culture plate.

3. Design and implement an intervention promoting judicious antimicrobial use. Again, using a pediatric age population as an example, develop and implement an intensive program to reduce the rate of antibiotic use focusing on pediatric providers and the children's parents from one of the study groups. The control group would allow comparison of outcomes. Techniques with proven effectiveness, such as face-to-face discussions with ''peer-counselors,'' would be an important component of such an intervention. Educational materials for physicians, including written guidelines for diagnosis and management of common respiratory conditions established in collaboration with professional organizations, and materials to educate parents on the potential adverse effects of unnecessary antibiotic use would be made available from CDC. Materials may also be developed by the recipient for use in the intervention. Other techniques that may be applicable in some settings include providing feedback to physicians comparing their practices with those of their colleagues and providing incentives which promote judicious antimicrobial use.

4. Measure effect of the intervention. Measure the differences in the rate of antimicrobial resistance among isolates obtained from carriers or persons with infection in the intervention and control groups. Other appropriate measures or analyses could include: (a) differences between control and intervention groups in rates and types of antimicrobial use; (b) differences in carriage or infection with resistant bacterial pathogens among family members or the community in general; (c) differences in the rate of recurrent or refractory infections; and (d) changes in parent or provider knowledge and attitudes regarding antimicrobial use.

5. Disseminate research findings. Disseminate research results by appropriate methods such as publication in journals, presentation at meetings, conferences, etc.

B. CDC Activities

1. Research Project Grants. A research project grant is one in which substantial programmatic involvement by CDC is not anticipated by the recipient during the project period. Applicants for grants must demonstrate an ability to conduct the proposed research with minimal assistance, other than financial support, from CDC. This would include documenting that applicant has sufficient resources for clinical, laboratory, and data management services, and for demonstrating a level of scientific expertise to achieve the objectives described in the research proposal without substantial technical assistance from CDC.

2. Cooperative Agreements. In a cooperative agreement, CDC will assist recipients in conducting the proposed research. The application should be presented in a manner that demonstrates the applicant's ability to address the research problem in a collaborative manner with CDC. In addition to the financial support provided, CDC will collaborate by: (1) Providing technical assistance in the design and conduct of the research including intervention methods and analytic approach; (2) performing selected laboratory tests as appropriate; and (3) participating in data management, the analysis of research data, and the interpretation and presentation of research findings.

C. Determination of Which Instrument To Use

Applicants must specify the type of award for which they are applying, either grant or cooperative agreement. CDC will review the applications in accordance with the Evaluation Criteria section of this announcement. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial CDC involvement in the project.

Notice of Intent To Apply

In order to assist CDC in planning for and executing the evaluation of applications submitted under this announcement, all parties intending to submit an application are requested to inform CDC of their intention to do so at their earliest convenience prior to the application due date. Notification should include: (1) Name and address of institution, and (2) name, address, and phone number of contact person. Notification should be provided by facsimile, postal mail, or E-mail to Greg Jones, M.P.A., National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop C–19, Atlanta, Georgia 30333, E-mail gjj1@cidod1.em.cdc.gov, facsimile (404) 639–4195.

Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria:

1. Background and Need (15 points). Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this grant/cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this program.

2. Capacity (35 points total):

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. (10 points)

b. 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. (20 points)

c. Extent to which applicant includes letters of support from non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate as described in the operational plan. (5 points)

3. Objectives and Technical Approach (50 points total):

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this program and which are measurable and time-phased. (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. Extent to which applicant clearly identifies specific assigned responsibilities for 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 study objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. 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: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) the proposed justification when representation is limited or absent; (3) a statement as to whether the design of the study is adequate to measure differences when warranted; and (4) 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. (20 points)

c. Extent to which applicant describes adequate and appropriate collaboration with CDC and/or others during various phases of the project. (10 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving project objectives. If the proposed project involves notifiable conditions, the degree to which applicant describes an adequate process for providing necessary information to appropriate State and/or local health departments. (10 points)

4. Budget (not scored): Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

5. Human Subjects (not scored): If the proposed project involves human subjects, whether or not exempt from the DHHS regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the ORG has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Executive Order 12372 Review

This program is not subject to Executive Order 12372 Review, Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the grant/cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR- supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of each application PHS Form 5161–1 (Revised 7/92, OMB Control Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, on or before August 6, 1996.

1. *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 objective 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.)

2. *Late Applications*: Applications which do not meet the criteria in 1. a. or 1. b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. An application package and business management and technical assistance may be obtained from Marsha Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–18, Room 300, Atlanta, GA 30305, telephone (404) 842–6523, E-mail address mdd2@opspgo1.em.cdc.gov, facsimile (404) 842–6513.

Programmatic technical assistance may be obtained from Dr. Benjamin Schwartz, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop C–09, Atlanta, GA 30333, telephone (404) 639–4747, E-mail address bxs1@ciddbd1.em.cdc.gov.

Important Notice: Atlanta, GA, will be the host of the 1996 Summer Olympics Games, July 19 through August 4, 1996. As a result of this event, it is likely that the Procurement and Grants Office (PGO), CDC, may experience delays in the receipt of both regular and overnight mail deliveries. Contacting PGO employees during this time frame may also be hindered due to the possible telephone disruptions. To the extent authorized, please consider the use of voice mail, E-mail, and facsimile transmission to the maximum extent practicable. However, do not fax lengthy documents or grant applications.

You may obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the Federal Register at http://www.access.gpo.gov).

Please refer to Announcement Number 662 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512- 1800.

Dated: June 21, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–16388 Filed 6–26–96; 8:45 am]

BILLING CODE 4163–18–P

[Announcement Number 644]

Ecology of the Deer Mouse (Peromyscus maniculatus) in Peridomestic Settings

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program to provide assistance for studies on the behavior, movement, reproductive biology, population structure, and relative infection status of deer mice (Peromyscus maniculatus) and deer-mouse populations inhabiting peridomestic environments.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section —Where To Obtain Additional Information.—)

Authority

This program is authorized under sections 301(a) and 317(k)(2) [42 U.S.C. 241(a) and 247b(k)(2)] of the Public Health Service Act, as amended. Applicable program regulations are found in 42 CFR Part 52, Grants for Research Projects.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children's Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day-care, health care and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Availability of Funds

Approximately $150,000 is available in FY 1996 to fund one award. It is expected that the award will begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Purpose

The purpose of this cooperative agreement is to assist the recipient in gaining knowledge about the behavior, movement, reproductive biology, population structure, and relative infection status of deer mice and deer-mouse populations inhabiting peridomestic environments. This knowledge will lead to improved assessment of the risk of hantaviral infection in peridomestic environments and more effective reservoir control and risk reduction. Because the major reservoir of Sin Nombre virus (SNV) in the western United States has been the deer mouse, the initial studies should concentrate on the ecology of this species. However, as more information about North American hantaviruses and their rodent hosts becomes available, additional studies of other virus/rodent pairings may be appropriate.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. below, and CDC will be responsible for conducting activities under B. below:

A. Recipient Activities

1. Locate an area containing a variety of structures (occupied, unoccupied, or seasonally occupied; houses, trailers, and outbuildings; heated and non-heated) where SNV infected deer mice are known to occur.

2. Use standard ecological and virological methods to monitor the dynamics of deer mouse populations and the dynamics of viral infection within host populations. Ecological techniques should include mark-recapture and/or radio telemetry studies. Virological techniques should be CDC approved and should include serology (on periodic blood samples taken from marked animals); methods may also include antigen-capture enzyme immunoassay and polymerase chain reaction for virus detection.

3. Studies similar to those outlined in #2 above with other virus/rodent relationships may be appropriate and should be considered as more information about North American hantaviruses and their rodent hosts becomes available.

4. Analyze and publish study results.

B. CDC Activities

1. Provide consultation and scientific and technical assistance to the recipient.

2. In collaboration with recipient, analyze study results.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Background and Need

Extent to which applicant demonstrates a clear understanding of the purpose and objectives of this proposed cooperative agreement. Extent to which applicant 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. (30 points)

B. Capacity

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project including appropriate laboratory facilities. 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 in this cooperative agreement as evidenced by curriculum vitae, publications, etc. (35 points)

C. Objectives and Technical Approach

Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and program requirements of this