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2682.

SUPPLEMENTARY INFORMATION: On Tuesday, November 7, 1995, there was published in the Federal Register, 60 FR 56153, a proposed consent agreement with analysis In the Matter of The Upjohn Company, et al., for the purpose of soliciting public comment.

Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to divest, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18) Donald S. Clark,
Secretary.

[FR Doc. 96-15495 Filed 6-18-96; 8:45 am]

BILLING CODE 6750-01-M

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: Cancellation of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board meeting previously scheduled for Thursday, June 20, 1996, is hereby cancelled. The next meeting will be held on Thursday, July 25, 1996, for which due notice will be given.

FOR FURTHER INFORMATION CONTACT:

Ronald S. Young, Executive Staff
Director, 750 First St., N.E., Room 1001,
Washington, D.C. 20002, or call (202)
512-7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92-463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101-6.1015 (1990).

Dated: June 14, 1996.

Ronald S. Young,
Executive Director.

[FR Doc. 96-15586 Filed 6-18-96; 8:45 am]

BILLING CODE 1610-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 663]

Applied Research in Emerging Infections—Genetics of Antimicrobial Resistance and Novel Methods for Detection of Antiviral Resistance

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 grant/cooperative agreement program to conduct research on the genetic analysis of antimicrobial resistance determinants.

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 and 317 of the Public Health Service Act, as amended (42 U.S.C. 241 and 247b).

Smoke-Free Workplace

The 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 up to three awards. It is expected that the average award will be \$125,000, ranging from \$80,000 to \$250,000.

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 the emerging infections extramural research program, the purpose of this grant/cooperative agreement announcement is to provide assistance for projects addressing the following two focus areas:

1. Mechanisms of Dissemination of Antimicrobial Resistance Genes

The focus of the investigations should be the examination of the role of plasmids, transposons, and integrons in antimicrobial resistance gene dissemination, the natural variation of the nucleotide sequences of resistance genes, and the impact of those changes on the resistance phenotype mediated by the genes. This should include examination of the role of antimicrobial use in institutions and its effect on gene dissemination. Assistance under this focus area will be provided for projects specifically addressing either of the following:

a. Improving understanding of the mechanisms by which vancomycin resistance genes in enterococci or genes encoding extended-spectrum β -lactamases in *Klebsiella pneumoniae* are spread in hospitals or other healthcare institutions (including nursing homes and clinics) and become part of the endemic flora of the institution.

b. Improving understanding of the mechanisms by which macrolide resistance genes (such as those encoding erythromycin resistance) are acquired and disseminated in *Streptococcus pneumoniae* in communities.

2. Antiviral Susceptibility Determination Methods:

Development of improved methods for measuring the susceptibility of herpes simplex virus (HSV) isolates to acyclovir. Current methods for measuring drug

susceptibility of HSV isolates are labor-intensive, expensive, and have not been standardized. These shortcomings stand as impediments to surveillance for acyclovir-resistant HSV or resistance in other viral pathogens. Specifically, assistance will be provided for projects focusing on development of assays based on novel methods or approaches for measuring the susceptibility of HSV to acyclovir. Such assays should be capable of providing results comparable to current plaque reduction and dye-uptake assays.

Applicants may submit separate applications for projects under one or both focus areas.

Program Requirements

Recipients may separately apply and receive support for projects under one or both of the two focus areas. In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A.1. or A.2. (depending upon which focus areas the recipient applies and receives support for) and CDC shall be responsible for conducting activities under B., below:

A. Recipient Activities

1. Mechanisms of Dissemination of Antimicrobial Resistance Genes

a. *Select study sites:* Study sites may include (a) one or more hospitals or related health care institutions known to have endemic or emerging problems with antimicrobial-resistant organisms in which extensive monitoring of antimicrobial-resistant strains has been conducted or (b) communities with extensive active surveillance.

b. *Collect isolates with corresponding epidemiologic and clinical data:* Assure that the isolates are well characterized with respect to phenotype, genotype, and mode of transmission from patient to patient. Collect bacterial strain typing information such as that derived by pulsed-field gel electrophoresis (PFGE), arbitrary primed polymerase chain reaction (PCR), restriction fragment length polymorphism (RFLP), plasmid fingerprinting, serotyping, or other highly discriminatory strain typing methods. Obtain antibiograms expressed as minimal inhibitory concentrations (MICs) of common antibiotics. One example of an appropriate approach to collection of isolates and data would be to assemble a series of isolates of vancomycin-resistant enterococci (VRE) from a single hospital with the corresponding PFGE data documenting the routes of transmission of the isolates among patients in the institution. The overall rates of infections over several

years and the diversity of strains present in the institutions or communities would be determined. This would presumably involve microbiology laboratories, infection control practitioners (for health care institutions), public health officials, and epidemiologists. Additionally, collection of data regarding antimicrobial use (expressed as Defined Daily Doses per 1000 patient-days) by area of the institution (e.g., intensive care unit or other inpatient ward) or in communities would be useful.

c. *Characterize the resistance determinants present by phenotypic and molecular methods:* Obtain MICs to an extended array of antimicrobial agents to classify the phenotype (e.g., teicoplanin to distinguish VanA from VanB). Determine strain types (when appropriate), the presence of plasmids or other genetic elements, and the presence of resistance genes in the strains as identified by using DNA probes or specific PCR, LCR, or other genetic assays.

d. *Monitor transmission and evaluate data:* Characterize the resistance genes present in the isolates, the modes of genetic exchange of the resistance determinants among isolates in the institutions or communities, and determine whether changes in the DNA or amino acid sequences of the genes are associated with broadening of the phenotype of the isolates carrying the genes. Consider the influence of antimicrobial use on frequency and mode of gene transmission and on changes in the phenotype of the isolates. Depending on the studies conducted, questions that could be addressed include: (1) Is an initial period of plasmid transfer among organisms followed by dissemination of a transposable element to multiple plasmids in strains of enterococci resulting in the vancomycin resistance phenotype being present in multiple strains of enterococci (as evidenced by widely divergent pulsed-field gel electrophoresis types)? (2) Do changes in the sequence of vanB correlate with increased resistance to teicoplanin? (3) Do the mode of transfer and the phenotype vary by antimicrobial use patterns in the institution or in certain wards of the institution?

e. *Disseminate research findings:* Disseminate research results by appropriate methods such as publication in journals, presentation at meetings and conferences, etc.

2. Antiviral Susceptibility Determination Methods

a. *Study isolates:* Identify a source of HSV isolates for study. Ideally, this

should include isolates from fresh clinical specimens that can be tested in parallel with the plaque reduction or dye uptake methods and for which acyclovir resistance has previously been documented.

b. *Devise a novel assay for determining the level of acyclovir susceptibility of clinical HSV isolates:* Establish a quality control system to insure the reproducibility of the assay. A quality control strain of HSV should be designated as part of the testing method and data showing its effectiveness should be established. A useful novel assay should be at least equivalent in performance and (ideally) substantially less expensive than current assays. The new method should be adaptable to a high-throughput, semi-automated format. Establish criteria for designating HSV isolates as "susceptible" or "resistant" to acyclovir.

c. *Evaluate the performance of the new assay in comparison with the plaque reduction assay.* To be useful for surveillance of resistance, any new assay should be substantially equivalent to those in current use (Am. J. Med. 73:380-382, 1982).

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 possessing sufficient resources for clinical, laboratory, and data management services and a level of scientific expertise to achieve the objectives described in their 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; (2) performing selected laboratory tests as appropriate; (3) participate in data management, the analysis of research data, and the interpretation and presentation of research findings; and

(4) providing biological materials (e.g., strains) as necessary for studies, etc.

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. Before issuing awards, CDC will inform the proposed grantee 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 Program 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, 2) name, address, and phone number of contact person, and 3) under which focus area(s) application(s) will be submitted. Notification should be provided to Greg Jones, M.P.A., by facsimile (404) 639-4195, E-mail gjj1@cidod1.em.cdc.gov or postal mail at National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop C-19, Atlanta, Georgia 30333.

Application Process

Applicants may apply for assistance for projects in one or both of the specific programmatic focus areas identified under Purpose and Program Requirements above. If applying for assistance for more than one of the two focus areas, a separate and complete application must be submitted for each project/focus area.

Evaluation Criteria

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

1. Background and Need (20 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 grant/cooperative agreement program.

2. Capacity (40 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. (10 points)

3. Objectives and Technical Approach (40 points total):

a. Extent to which applicant describes specific 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. (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 and describes appropriate study sites (per Recipient Activities 1.a.) or HSV isolates (per Recipient Activities 2.a.). 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 objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives.

If the proposed project involves human subjects, 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.

(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 will be documented. (see Other Requirements for additional information regarding this requirement for research projects). (15 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. (5 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.

Executive Order 12372 Review

This program is not subject to Executive Order 12372, 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. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. 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 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 exists 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 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 Form PHS-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 300, Mailstop E-18, Atlanta, Georgia 30305, Attention: Marsha Driggans, on or before August 5, 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, Georgia 30305, telephone (404) 842-6523, E-mail mdd2@opspgo1.em.cdc.gov, facsimile (404) 842-6513.

Programmatic technical assistance may be obtained from Dr. Fred C. Tenover, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G-08, Atlanta, Georgia 30333, E-mail fnt1@cidhip1.em.cdc.gov, telephone (404) 639-3246.

Please refer to Announcement Number 663 when requesting information regarding this program.

Important Notice: Atlanta, Georgia, 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>).

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 11, 1996.

Joseph R. Carter,

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

[FR Doc. 96-15558 Filed 6-18-96; 8:45 am]

BILLING CODE 4163-18-P

[Announcement Number 532A]

Cooperative Agreements for a National System of Integrated Activities To Prevent HIV Infection and Other Serious Health Problems Among Students, Especially Postsecondary Students and Those in High-Risk Situations

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for cooperative agreements to establish a national system of integrated activities for preventing HIV infection and other serious health problems among the nation's students, especially postsecondary students and those in high-risk situations. This program announcement is an amendment to Announcement Number 532 published in the Federal Register on June 16, 1995, pages 31721 through 31724 [60 FR 31721]. (A cooperative agreement is a legal agreement in which CDC provides financial assistance and substantial programmatic assistance to the recipient during the project.)

The CDC is committed to implementing the recommendations outlined in the External Review of HIV Prevention Strategies and 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 program announcement is related to the priority areas of Health Promotion and Preventive Services with a particular focus on HIV Infection Objective 18.11, to "Provide HIV education for students and staff in at least 90% of colleges and universities";