

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 the 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 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.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions." An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research

Risks at the National Institutes of Health.

Application Submission and Deadline

The original and two copies of the 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, Attention: Marsha Driggans, on or before August 23, 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. Business management 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., Room 314, Mailstop E-18, Atlanta, GA 30305, telephone (404) 842-6523, facsimile (404) 842-6513, E-mail mdd2@opspgo1.em.cdc.gov or CDC WONDER.

Programmatic technical assistance may be obtained from Robert Pinner, M.D., or Pat McConnon, M.P.H., Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C-12, 1600 Clifton Road, NE., Atlanta, GA 30333, telephone (404) 639-2603. E-mail address for Dr. Pinner: rwp1@cidod1.em.cdc.gov or CDC WONDER. E-mail address for Mr. McConnon: pjm2@cidod1.em.cdc.gov or CDC WONDER.

Please refer to Announcement Number 655 when requesting information and submitting and application.

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>).

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.

Potential applicants may obtain a copy of "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States" through the Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Office of Planning and Health Communication—EP, Mailstop C-14, 1600 Clifton Road, Atlanta, GA 30333. Requests may also be sent by facsimile to (404) 639-3039.

Dated: June 21, 1996.

Joseph R. Carter,

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

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[Announcement Number 664]

Primate Model for Studying the Pathogenesis of Measles Infections and for Development of Improved Measles Vaccines

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement

program to support research into the pathogenesis of measles virus in a primate model. The goal of this program is to assist researchers in defining the mechanism of immune protection from measles virus and to use this information to develop improved vaccines for worldwide measles control efforts.

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. (To order 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)(1) [42 U.S.C. 241(a) and 247b(k)(1)] 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 \$200,000 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 the 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 developing a primate model for measles infection and in conducting studies to: (1) improve the infection model, (2) characterize the immune response to natural disease and vaccination, (3) develop and test experimental measles vaccines, and (4) investigate the pathogenesis and epidemiology of measles infections.

More specifically, the purpose of the program is to achieve the following research goals:

1. Characterization of the immune response to natural disease and vaccination. Studies should attempt to measure differences between the immune response in animals receiving measles vaccination to those experiencing infection with a virulent strain. Efforts should be aimed at providing a complete description of the humoral and cellular immune responses and should also attempt to measure mucosal immunity.

2. Development of a vaccine that will protect in the presence of maternal antibody. The goal of these studies should be to develop a vaccine that will protect newborns from measles infection during the first year of life and not interfere with subsequent vaccination using standard vaccines.

3. Evaluation of immune response to individual measles virus antigens. Research should be designed to measure the immune response generated by experimental measles vaccines and the degree of protection provided. Measures of mucosal and cellular immunity as well as immune memory will be particularly important.

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.

A. Recipient Activities

1. Develop study design to accomplish the research goals described above.

2. Perform all inoculations of animals. Maintain records of clinical observations and obtain samples for laboratory analysis.

3. Perform laboratory analysis of samples obtained from study animals.

4. Provide routine veterinary care, housing and other support for rhesus macaques to be used in experiments. Comply fully with PHS policies regarding research on animal subjects.

5. Maintain sufficient numbers of seronegative animals so that experiments can be completed within an appropriate amount of time.

6. Develop experimental measles vaccines and evaluate them in the animal model.

7. Analyze data and prepare manuscripts describing results of research investigations.

B. CDC Activities

1. Provide technical assistance and advice for design and conduct of the research.

2. Provide assistance in development of various preparations of measles virus antigens for use as experimental vaccines. This material may consist of vaccines derived of recombinant DNA technology.

3. Provide specialty reagents such as monoclonal and polyclonal antiserum and PCR primers as necessary.

4. Assist in conducting specialized analysis of samples obtained from test animals. These may include special serological or immunologic assays, as well as assays to detect and measure measles virus or measles virus RNA in various tissue samples. Perform genetic characterization of viruses used in the study.

5. Assist in data analysis.

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 telephone number of contact person. Notification should be provided by facsimile, postal mail, or E-mail to Paul Rota, Ph.D., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G-17, Atlanta, GA 30333, E-mail par1@ciddvd1.em.cdc.gov, facsimile (404) 639-1307.

Evaluation Criteria

All applications will be reviewed and evaluated according to the following criteria (100 total points):

1. Background and Need (10 total points)

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

2. Capacity (55 total points)

a. Extent to which applicant describes adequate resources and facilities for conducting the project. Extent to which facilities for the safe handling of infectious agents are available. (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 in this cooperative agreement as evidenced by curriculum vitae, publications, etc. Extent to which the applicant demonstrates experience with virology, particularly the virology of measles virus. (10 points)

c. Extent to which applicant demonstrates experience with viral pathogenesis/immunology in rhesus macaques or other primate system. Extent to which the applicant can demonstrate previous or ongoing experience with measles infections of primates. Extent to which the applicant can produce a measles infection that is similar to measles infections in humans in rhesus macaques following intranasal inoculation. (35 points)

3. Objectives and Technical Approach (35 total points)

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose and program requirements of this cooperative agreement and which are measurable and time-phased. (5 points)

b. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. (10 points)

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

d. Extent to which applicant provides a detailed plan for evaluating study results and for evaluating progress towards achieving project objectives. (10 points)

4. Budget (Not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

Executive Order 12372

Applications are not subject to review under 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

Animal Subjects

This proposed project involves research on animal subjects; therefore, the applicant must comply with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions." An applicant organization using vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health, Bethesda, Maryland.

Application Submission and Deadline

The original and two copies of application PHS Form 398 (Revised 5/95, OMB Number 0925-0001) 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, Attention: Marsha Driggans, on or before August 12, 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 independent review group.

(Applicants should 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 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 shall not be considered in the current competition for funding 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., Room 314, Mailstop E-18, Atlanta, GA 30305, telephone (404) 842-6523, E-mail mdd2@opspgo1.em.cdc.gov, facsimile (404) 842-6513.

Programmatic technical assistance may be obtained from Paul Rota, Ph.D., Supervisory Research Microbiologist, Measles Section, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G-17, Atlanta, GA 30333, telephone (404) 639-3308, E-mail par1@ciddvd1.em.cdc.gov, facsimile (404) 639-1307.

Please refer to Announcement Number 664 when requesting information regarding this program.

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Dated: June 21, 1996.

Joseph R. Carter,

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

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