

intestinal tissue obtained from matched controls.

3. Compare results between the two groups.

4. Provide the results of these studies to practicing physicians and other health care professionals.

Measurable outcomes of the program will be in alignment with the following performance goals for the National Immunization Program: (1) Reduce the number of indigenous cases of vaccine-preventable diseases, (2) ensure that two year olds are appropriately vaccinated, and (3) work with global partners to reduce the cumulative global measles related mortality rate.

B. Eligible Applicants

Assistance will be provided only to the American Academy of Pediatrics (AAP). No other applications are solicited. The potential role of the MMR vaccine as a cause of autism has divided segments of the medical, scientific and public communities and threatens to adversely effect the MMR immunization program in the United States as it has in the United Kingdom and Ireland, where MMR immunization rates have dropped sharply from above 95 percent to just over 70 percent. This sharp decrease came as a result of two published papers alleging an association between the MMR vaccine and Autism. To provide definitive data as to the potential link between measles antigen in the intestine and autistic disorder, groups and organizations which feel strongly that there either is or is not an association between MMR and autistic disorder must be involved in this study to ensure acceptance of the results. Groups that must be involved in this study include autism community representatives (MIND Institute, Cure Autism Now, Autism Society of America); research groups at Harvard University, Columbia University, Coombe Women's Hospital, Dublin, Ireland; CDC; other government representatives; and members of the general medical and scientific communities. AAP is the only organization that can ensure that these diverse groups, organizations and individuals come together to implement and complete this proposal. This is because AAP is the only major scientific and professional body with credibility among all of the groups with a stake in the outcome. AAP has made significant scientific contribution in the investigation of the possible association of MMR vaccine and Autism. AAP has been the only organization that has pulled these groups together in the past to evaluate MMR vaccine and autistic spectrum disorder. In June 2000, AAP

convened a conference at which parents, practitioners, and scientists presented information on MMR and ASD. AAP then formed a multidisciplinary panel of experts who reviewed data on the pathogenesis, epidemiology, and genetics of ASD and the available data on the hypothesized associations with Intestinal Bowel Disease, measles, and MMR vaccine. AAP's findings were published in the May 2001 issue of Pediatrics. ["Measles-mumps-rubella vaccine and autistic spectrum disorder: report from the new challenges in childhood immunizations conference convened in Oak Beach, Illinois, June 12-13, 2000". Pediatrics 2001; 107(5) [url:http://www.pediatrics.org/cgi/content/full/107/5/e84/](http://www.pediatrics.org/cgi/content/full/107/5/e84/)].

Additionally, because of AAP's broad scope of contacts, the organization's respect among pediatricians and other healthcare providers, data from this project can be facilitated and disseminated rapidly. The immunization recommendations and guidelines developed by AAP are considered among the most reliable and up-to-date information available to the pediatric community. When study findings are disseminated by AAP, immunization practices could be affected significantly.

C. Funds

Approximately \$450,000 is being awarded FY 2002. It is expected that the award will begin on or about August 30, 2002 and will be made for a 12-month budget period within a project period of up to two years. Funding estimates may change.

Continuation awards 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. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

For business management technical assistance, contact: Ms. Peaches Brown, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146. Telephone number 770-488-2738. E-mail address: prb0@cdc.gov.

For program technical assistance, contact: Maureen Kolasa, Epidemiologist, Centers for Disease

Control and Prevention, 1600 Clifton Road, NE., Mailstop E-52, Atlanta, Georgia 30333. Telephone number 404-639-8759. E-mail address: mxk2@cdc.gov.

Dated: October 4, 2002.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02186]

Oral Vaccine Institute; Notice of Award of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the award of fiscal year (FY) 2002 funds for a grant for Oral Vaccine Institute (OVI) research on liposome-based delivery systems for oral or nasal vaccination. This program addresses the "Healthy People 2010" focus areas of Immunization and Infectious Diseases; Maternal, Infant and Child Health; Medical Product Safety; and Sexually Transmitted Diseases.

The purpose of the program is to develop a platform of liposome constructs containing vaccine antigens that can immunize through the oral or nasal routes, rather than via parenteral injection with conventional needle and syringes.

B. Eligible Applicant

This grant is to be awarded to the Oral Vaccine Institute, which is affiliated with Oral Vaccine Technologies, Inc. (OVT), a for-profit company based in Las Vegas, Nevada and incorporated in Nevada. OVT owns several patents currently issued by the U.S. Patent office. They have assembled a team of scientists with considerable expertise in the areas of liposome development, vaccine development and mucosal immunity. OVT has executed an agreement allowing the Oral Vaccine Institute the right to use its intellectual property that is set forth and described in its Executive Summary for certain research purposes.

BioMedical Research Models, Inc. (BRM) is under contract to provide certain laboratory facility capabilities and personnel to accomplish the mission of the Oral Vaccine Institute. The facility is fully prepared to

administer and assist the proposed animal-based studies.

Acting in concert with these three organizations (OVI, OVT and BRM), and their scientific staffs and consultants, the Institute will develop platform technologies that could significantly impact the response to a bioterrorism attack.

Justification: This grant is awarded sole source by virtue of Congressional earmark evidenced in the following records of Congress: Senate-House Conference Committee, Calendar No. 193, 107th Congress Report-Senate; assessable in pages 88–89 of 229 of pdf document: http://frwebgate.access.gpo.gov/cgi-bin/grtdoc.cgi?dbname=107_cong_reports&docid=f:hr342.107.pdf

Note: Title 2 United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

C. Funds

Approximately \$1.2 million is being awarded in FY 2002. It is expected that the award will begin on or before September 15, 2002, and will be made for a 12 month budget period within a project period of one year. The funding estimate may change.

D. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on “Funding” then “Grants and Cooperative Agreements.”

For business management assistance contact: Peaches Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: 770–488–2738, e-mail address: prb0@cdc.gov.

For program technical assistance, contact: Dr. Bruce Weniger, Vaccine Safety and Development Activity, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road mailstop E–61, Atlanta, GA 30333, Telephone: 404–639–8779, e-mail address: bgw2@cdc.gov.

For program administrative assistance, contact: Sharon Holmes, Program Analyst, Vaccine Safety and Development Activity, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road mailstop E–61, Atlanta, GA

30333, Telephone: 404–639–8582, e-mail address: sholmes@cdc.gov.

Dated: October 4, 2002.

Sandra R. Manning,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3109–N]

Medicare Program; Town Hall Meeting on the Hospital “1-hour” Rule Related to the Use of Restraint and Seclusion

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a town hall meeting to obtain and discuss general comments from the public concerning the impact of the hospital “1-hour” rule related to the use of restraint and seclusion. Specifically, the meeting will attempt to solicit individual comments and experiences from providers, advocates, consumers, and other interested parties concerning the application of the “1-hour” rule requiring a physician or a licensed independent practitioner to make a face-to-face assessment within 1 hour of any patient being placed in restraint or seclusion for behavioral reasons. We are particularly interested in data that show how this requirement may be imposing burdens on patient care, including, but not limited to, financial burdens on hospitals and physicians. We would be happy to address/discuss other concerns related to the provision of hospital services to this population of patients.

Hospitals, provider representatives, advocacy groups, physicians, and other interested parties are invited to this meeting to present their views on this issue. The opinions and alternatives provided during this meeting will assist us as we evaluate our policy on the “1-hour” rule. The meeting is open to the public, but attendance is limited to space available.

DATES: *Meeting Date:* The town hall meeting announced in this notice will be held on Tuesday, October 29, 2002, from 10 a.m. to 1 p.m. (eastern standard time).

ADDRESSES: The town hall meeting will be held in the auditorium at the Centers for Medicare & Medicaid Services, 7500

Security Boulevard, Baltimore, MD 21244.

FOR FURTHER INFORMATION CONTACT: Nancy Archer (410) 786–0596. You may also send inquiries about this meeting via e-mail to narcher@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 2, 1999, we published an interim final rule with comment introducing a new Patients’ Rights Condition of Participation (CoP) that hospitals must meet to be approved for, or to continue participation in, the Medicare and Medicaid programs (64 FR 36070). One of the requirements mandates that, for restraint or seclusion applied for behavioral reasons, a physician, or licensed independent practitioner (LIP), must make a face-to-face assessment of that patient within 1 hour of implementation of the intervention (64 FR 26088).

The “1-hour” requirement was subsequently challenged in the United States District Court for the District of Columbia. Although the Court ruled in the Secretary’s favor with respect to this provision, hospitals and their provider groups have continued to inform us that requiring a physician or LIP to perform the 1-hour face-to-face assessment causes undue burden on hospitals, without specific evidence that the quality of care has improved.

II. Meeting Format

The meeting will begin with an overview of the goals of the meeting and an introduction of the meeting moderator, followed by remarks from Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services, and Charles G. Curie, Administrator, Substance Abuse and Mental Health Services Administration. The Acting Director, Office of Clinical Standards and Quality, will present the context for the discussion. Participants that have requested to speak will then be given time to present their information. The moderator will solicit comments and recommendations from the audience about issues concerning the implementation of the 1-hour rule, as time permits.

The information about the town hall meeting will be posted at the following website address: <http://www.cms.hhs.gov/opendoor/hospitals.asp>. At this address, interested parties will find an agenda for the meeting and instructions on how to call into the meeting if unable to attend in person.

We will limit the time for participants to make formal statements according to