

grant applications are available at <http://www.grants.gov/>.

SUPPLEMENTARY INFORMATION: All grant applicants must obtain a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number is free and easy to obtain from http://www.dnb.com/US/duns_update/.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, DC 20201, telephone: (202) 357-3440.

Dated: May 20, 2004.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Spina Bifida Information and Resource Development Center

Announcement Type: New.

Funding Opportunity Number: 04215.

Catalog of Federal Domestic

Assistance Number: 93.283.

Dates:

Letter of Intent Deadline: June 10, 2004.

Application Deadline: June 25, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act, (42 U.S.C. 247b(k)(2)), as amended.

Purpose: The purpose of the program is to prevent the recurrence of pregnancies affected by Neural Tube Defects (NTDs), expand local programs for those affected by spina bifida, promote research proposal development (not implementation), and expand information resources.

This program addresses the "Healthy People 2010" focus area(s) of Maternal, Infant and Child Health and Disability and Secondary Conditions.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center on Birth Defects and Developmental Disabilities: increasing consumption of folic acid among women of reproductive age to prevent serious birth defects, improving care, and improving the lives of people with spina bifida.

Activities: Awardee activities for this program are as follows: Applicants should provide evidence of the capacity to effectively address the following activities:

a. Evaluate the effectiveness of education materials previously developed for supplementation by assessing reported knowledge, consumption and subsequent pregnancy outcomes of the target audience.

b. Develop training for health care providers (HCP) designed to increase the number of women receiving counseling about consuming adequate levels of folic acid.

c. Develop and implement a plan to evaluate the efficacy and effectiveness of this project.

d. Implement a pilot program to support the development of competencies among professionals in developing proposals for submission to Federal and other funding agencies to further spina bifida research consistent with evidence-based research priorities.

e. Evaluate the effectiveness of the pilot development program designed to develop competency in professionals related to proposal development for research in spina bifida.

f. Implement and evaluate a program for self-determination to improve the quality of life of individuals with spina bifida and their families.

g. Expand a national resource center for spina bifida information and dissemination.

h. Develop an evaluation plan for tracking the volume, kinds of requests, and responses to requests and inquiries made to the Resource Center for use in enhancing the effectiveness and responsiveness of the Center.

II. Award Information

Type of Award: Grant.

Fiscal Year Funds: Fiscal Year 2004.

Approximate Total Funding: \$950,000.

Approximate Number of Awards: One.

Approximate Average Award: \$950,000. This amount is for the first 12-month budget period, and includes both direct and indirect costs.

Floor of Award Range: Minimum award \$900,000.

Ceiling of Award: \$950,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Two years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and

the determination that continued funding is in the best interest of the Federal government.

III. Eligibility Information

III.1. Eligible Applicants

Assistance will be provided only to applicants that are well-established national, nonprofit organizations with state chapters that have expertise in: (1) Developing health education messages for women at risk of having a NTD-affected pregnancy; (2) developing State chapters to improve the health of individuals with spina bifida and their families; and (3) developing a central resource information and education center about spina bifida.

To be eligible, applicants must:

1. Demonstrate that the organization's mission is explicitly committed to the prevention of NTDs specifically spina bifida, and the health and well being of individuals with spina bifida and their families as demonstrated by submission of the charter, articles of incorporation, or other governing documents.

2. Demonstrate that the organization is a nonprofit and recognized as tax exempt under section 501(c)(3) of the Internal Revenue Code, and this may be demonstrated through inclusion of your Internal Revenue Service determination letter.

3. Demonstrate the organization has capacity and experience in providing health education to women who are at risk of having a NTD-affected pregnancy, and this may be demonstrated through letters of support.

4. Demonstrate that the organization has a national membership and a national network of State and local chapters; this may be done through a letter from the organization's leadership which describes the national network.

5. Demonstrate the presence and functions of a national information and resource center that is capable of expansion.

This information should be placed directly behind the face page (first page) of your application. Applications that do not include the above information will be determined as non-responsive and will be returned without review.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application

did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Note: Title 2 of the 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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: (770) 488-2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): CDC requests that you send a LOI if you intend to apply for this program. Your LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review. Your LOI must be submitted in the following format:

- Maximum number of pages: Two.
- Font size: 12-point unrounded.
- Single-spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon.

Content: Your LOI must contain the following information: Name, address, and telephone number of the Principal Investigator; names of other key personnel; participating institutions; number and title of the program announcement.

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 35. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unrounded.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.

- Printed only on one side of page, double spaced.

- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items which correspond to the evaluation criteria: Plan, Methods, Objectives, Timeline, Staff, Understanding, Need, Performance Measures, Budget Justification, etc. The budget justification will not be counted against the stated page limit.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information may include: curriculum vitae, resumes, organizational charts, letters of support, graphic presentations of time-bounded work plans, etc.

Applicants must submit a separate typed abstract of their proposal consisting of no more than two single-spaced pages. Applicants should also include a table of contents for the project narrative and related attachments.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy, and there is no charge.

To obtain a DUNS number, access the following Web site: <http://www.dunandbradstreet.com> or call 1-866-705-5711.

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcommnt.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

LOI Deadline Date: June 10, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level

of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: June 25, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: (770) 488-2700. Before calling, please wait three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed Federal assistance applications. You should contact your State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your State's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows: Grant funds may be used to

support personnel services, supplies, equipment, travel, subcontracts, and other services directly related to project activities consistent with the approved scope of work. Grant funds cannot be used to supplant other available applicant or collaborating agency funds, for construction, for purchase of facilities or space, or for patient care. Grant funds cannot be used for individualized services (direct patient support) such as for wheelchairs, medical appliances, or assistive technology unless specifically approved by the funding agency. Grant funds cannot be used for the conduct of research.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects, and Developmental Disabilities, 1600 Clifton Road, Mailstop: E-87, Atlanta, GA 30333. Telephone (404) 498-3979, fax (404) 498-3060, e-mail: lgt1@cdc.gov.

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA#04215, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the identified objectives of the grant. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

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

1. Scope of Proposal (30 Points)

This addresses the applicant's capacity to fully and effectively carry out project activities on a national scale as noted in the Announcement. This includes how well the activities proposed will achieve project goals and how the applicant anticipates and utilizes innovative and valued approaches in meeting all requirements of the Announcement. This also includes how well the applicant accounts for working with collaborating entities and partners toward meeting the purpose of the project.

2. Description of Objectives (25 Points)

This assesses whether the proposed goals and objectives are clearly stated, realistic, time-phased, adequately detailed, capable of tracking, and related to the purpose of the project. It includes how well the goals and objectives encompass all relevant components of the work required under the Announcement with attention to individual, interdependent, and synergistic relationships among all elements of the Program Requirements.

3. Project Personnel (20 Points)

This includes an evaluation as to whether all personnel proposed to be involved in this project are fully qualified, with evidence of experience and evidence in past activities and achievements appropriate to a project of this magnitude and scope. It also includes whether the stated responsibilities for requested personnel and the proposed staffing functions will assure adequate progress toward meeting all goals and objectives.

4. Understanding of the Problem (15 Points)

This includes how well the applicant demonstrates full understanding of the range of work requirements, potential problems, and complexities of the project. It also covers how well the applicant provides background information for the tasks envisioned such that framework and foundation described directly demonstrates that the plan proposed to conduct the project will be effective and successful.

5. Evaluation (10 Points)

This includes the review of the applicant's evaluation plan for the design and management of the individual and multiple initiatives proposed in the conduct of the project. This includes the funding agency's review of the applicant's planning protocol for new activities as well as the applicant's capacity to assess and monitor the performance and success of

ongoing activities implemented over the life of the project.

6. Budget (Not Scored)

How well does the applicant provide justification for budget expenditures as well as appropriateness to activities proposed in the application? The budget will be evaluated for the extent that it is reasonable, clearly justified, and consistent with the intended use of the grant funds.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center on Birth Defects and Developmental Disabilities. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

V.3. Anticipated Award Date

September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements.
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR-7 Executive Order 12372.

- AR-8 Public Health System Reporting Requirements.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.
- AR-15 Proof of Non-Profit Status.
- AR-22 Research Integrity.
- AR-24 Health Insurance Portability and Accountability Act Requirements.
- AR-25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.
 - c. New Budget Period Program Proposed Activity Objectives.
 - d. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: (770) 488-2700.

For program technical assistance, contact: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E-87, Atlanta, GA 30333. Telephone: (404) 498-3979, e-mail: lgt1@cdc.gov.

For financial, grants management, or budget assistance, contact: Sylvia Dawson, Grants Management Specialist, Procurement and Grants Office, CDC,

2920 Brandywine Road, Suite 300, Atlanta, GA 30341. Telephone: (770) 488-2771, e-mail: snd8@cdc.gov.

Dated: May 20, 2004.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Effect of West Nile Virus Infection on Outcomes of Pregnancy in Humans

Announcement Type: New.

Funding Opportunity Number: 04213.

Catalog of Federal Domestic

Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: June 15, 2004.

Application Deadline: July 6, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) of the Public Health Service Act, (42 U.S.C. 247b(k)(2)), as amended.

Purpose and Research Objectives: The purpose of the program is to determine whether West Nile Virus (WNV) infection of pregnant women has adverse effects on the outcomes of pregnancy and to measure and describe the effects, if any, on the health of children born to women who were infected with WNV during their pregnancy.

This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities: To improve the understanding and find the causes and risk factors for birth defects and developmental disabilities in order to develop prevention strategies.

WNV, a single-stranded RNA flavivirus with antigenic similarities to Japanese encephalitis and St. Louis encephalitis viruses, is transmitted to humans primarily through the bite of infected mosquitoes. Flavivirus infection during pregnancy has been rarely associated with both spontaneous abortion and neonatal illness, and these viruses have not been known to cause birth defects in humans. In 2002, a 20-

year old woman developed WNV encephalitis during the 27th week of pregnancy. At 38 weeks of gestation she delivered a live infant who appeared normal but on further examination had chorioretinitis and cystic cerebral tissue destruction. Tests for cytomegalovirus, rubella virus, herpes simplex virus, lymphocytic choriomeningitis virus, enterovirus, and toxoplasma provided no evidence that any of these agents had infected the infant. IgM antibody to WNV was found in cord blood and in the infant's serum and cerebrospinal fluid, indicating that the infant had acquired WNV infection in utero. WNV nucleic acid was found in the placenta and umbilical cord tissue. Although it is not possible to establish a direct link between WNV and the abnormalities seen in this infant, the abnormalities observed are consistent with those observed in intrauterine infections with other agents, suggesting that they may be related to WNV intrauterine infection. Three other instances of maternal WNV infection were investigated in 2002; in all three instances the infants were born at full term with normal appearance and without laboratory evidence of WNV infection, but cranial imaging studies and ophthalmologic examinations were not performed.

During 2002 a total of 4,156 cases of WNV illness in humans, including 2,942 cases of neuroinvasive disease, were reported to the Centers for Disease Control and Prevention (CDC) from state health departments. During 2003 over 9,100 cases of WN illness, including over 2,600 cases of neuroinvasive disease were reported to CDC. CDC is currently following over 70 women who were reported to have had WNV disease during pregnancy in 2003.

The proportion of WNV infections during pregnancy that result in congenital infection of the newborn is unknown. The spectrum of clinical abnormalities associated with intrauterine infections with other agents is wide and includes embryonic death and resorption, abortion and stillbirth, prematurity, intrauterine growth retardation and low birth weight, developmental anomalies and teratogenesis, congenital disease, and persistent postnatal infection. The case described above from 2002 suggests that intrauterine transmission of WNV in some instances may have deleterious consequences, but the spectrum of abnormalities and degree of risk of intrauterine transmission are currently unknown. Improved understanding of these issues is essential to allow appropriate counseling of women