

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Capacity Development for International Organizations Engaged in War-Related Injuries and Mine Action

Announcement Type: New.

Funding Opportunity Number: 04121.

Catalog of Federal Domestic

Assistance Number: 93.283.

Key Dates:

Application Deadline: June 1, 2004.

I. Funding Opportunity Description

Authority: Sections 301, 307, and 317 of the Public Health Service Act, [42 U.S.C., Sections 241, 242I, and 247(b)], as amended.

Purpose: The purpose of the program is to increase the public health capacity of United Nations Organizations mandated with addressing and coordinating responses to and prevention of war-related injuries in less developed countries. This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention and Environmental Health.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Environmental Health (NCEH): Increase the understanding of the relationship between environmental exposures and health effects.

Activities: Awardee activities for this program are as follows:

- Use a public health approach to evaluate standard methods of mine risk education (MRE) and develop a best practices approach for MRE.
- Design, implement, evaluate, and disseminate information from surveillance systems for injuries in post-conflict settings.
- Develop mechanisms for assessing the impact of sexual violence in conflict settings, and mitigating its impact on affected populations.
- Develop public health training curricula and conduct training courses for war-related injury and mine action field staff.
- Work with CDC staff to plan dissemination strategies of lessons learned from this program to inform the war-related injury community.
- Establish and document the utility of a comprehensive public health approach to war-related injuries and mine action.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide technical assistance in the design and implementation of evaluation of MRE programs, MRE strategies and assessing sexual violence.
- Collaborate on the synthesis and dissemination of lessons learned from the program.
- Provide instructors for training courses and other capacity building programs.
- Provide technical assistance and guidance for designing, implementing and maintaining surveillance systems.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$400,000.

Approximate Number of Awards: Three.

Approximate Average Award: \$75,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: \$20,000.

Ceiling of Award Range: None.

Anticipated Award Date: August 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Five 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

Applications may be submitted by United Nations organizations mandated by United Nations member-states with the global coordination of war-related injury and mine action activities.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

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

Eligibility is limited to United Nations organizations because these organizations are mandated by United Nations member-states to coordinate

diverse war-related injury and mine action activities. Only organizations with these mandates have the resources and access to perform these activities and to assure the greatest impact on the larger war-related injury community.

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

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

- Maximum number of pages: 10. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12-point unredlined.
- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- 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 in the order listed:

- Project plan.
- Understanding of topic.
- Staff.
- Timeline.
- Evaluation plan.
- Budget justification (not counted in 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 includes:

- Curriculum Viteae.
- Organizational Charts.
- Letters of Support.

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 <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/pubcomm.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

Application Deadline Date: June 1, 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 program 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 two to three days

after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows: Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives, however, prior approval by CDC officials must be requested in writing.

The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut, and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required).

All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

You must obtain annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

If you are a domestic organization and 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

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04121, 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 various identified objectives of the cooperative agreement. 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.

Your application will be evaluated against the following criteria:

- Project plan (30 points) Will the project plan meet the objectives of this cooperative agreement?
- Understanding of topic (20 points) Is the applicant's understanding of the program sufficient for implementation?
- Staff (20 points) Does the applicant's staff have sufficient experience and skill for the program?
- Timeline (15 points) Is the timeline appropriate for the scope of proposed activities?
- Evaluation plan (15 points) Is the proposed evaluation protocol for the proposed activities sufficient?
- Budget justification (not counted in page limit).

V.2. Review and Selection Process

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

An objective review panel will evaluate your application according to the criteria listed in the "V.1. Criteria" section above.

V.3. Anticipated Announcement Award Date

August 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-8 Public Health System Reporting Requirements.
- AR-9 Paperwork Reduction Act Requirements.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.
- AR-16 Security Clearance Requirement.
- 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 Requirements

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. Detailed Line-Item Budget and Justification.

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 sent to the Grants Management 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: Michael Gerber, Project Officer, 4770 Buford Hwy NE, Mailstop F-48, Atlanta, Georgia 30341, Telephone: 770-488-3520, E-mail: mcg9@cdc.gov.

For budget assistance, contact: Steward Nichols, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2788, E-mail: shn8@cdc.gov.

Dated: March 24, 2004.

Edward Schultz,

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

[FR Doc. 04-7028 Filed 3-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee (SRSHEs): Cancellation of Meeting

This notice announces the cancellation of a previously announced meeting.

Federal Notice Citation of Previous Announcement: March 11, 2004 (Volume 69, Number 48) [Notices] [Page 11635]

From the **Federal Register** Online via GPO Access.

Previously Announced Time and Date: 8 a.m.-3:30 p.m., April 6, 2004.

Place: Adam's Mark Hotel Columbia, 1200 Hampton Street, Columbia, South Carolina 29201.

Change in the Meeting: This meeting has been canceled.

FOR FURTHER INFORMATION CONTACT:

Phillip Green, Executive Secretary, SRSHEs, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE. (E-39), Atlanta, Georgia 30333, telephone (404) 498-1800, fax (404) 498-1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: March 23, 2004.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-7022 Filed 3-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0117]

International Conference on Harmonisation; Draft Guidance on E2E Pharmacovigilance Planning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "E2E Pharmacovigilance Planning." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a method for summarizing the identified risks of a drug, the potential for important unidentified risks, and the potentially at-risk populations and situations that were not studied before the drug was approved. The draft guidance is intended to foster better and earlier planning of pharmacovigilance activities, especially in preparation for the early postmarketing period of a new drug.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2004.

ADDRESSES: Submit written comments on the draft guidance to the Division of