

the recipients of these services. This proposed collection, represents a revision of the SPR. This revision was undertaken for the following purposes: (1) The need to develop more permanent information requirements for the National Family Caregiver Support Program (enacted in 2000); (2) the need to comply with revised OMB standards for gathering information regarding race and ethnicity; and (3) the need to reduce the burden of the SPR/NAPIS requirements on States, area agencies and service providers.

AoA estimates the burden of this collection of information as follows: 2,606 hours.

Dated: May 27, 2003.

**Josefina G. Carbonell,**

*Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03106]

#### Development and Validation of Measures To Assess Outcomes of Mild Traumatic Brain Injury; Notice of Availability of Funds

*Application Deadline:* July 2, 2003.

#### A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 391, 317(k)(2), and 301(a) of the Public Health Service Act, (42 U.S.C. sections 280b, 247b(k)(2), and 241(a)). The Catalog of Federal Domestic Assistance number is 93.136.

#### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement for the development and validation of measures to assess outcomes of mild traumatic brain injury (MTBI). This program addresses the "Healthy People 2010" focus area, Injury and Violence Prevention.

The purpose of this program is to fund research to develop reliable and valid measures for assessing longer-term outcomes of mild traumatic injury. These measures should be applicable to future population-based studies of outcomes of MTBI to estimate the prevalence of MTBI-related disability (See Attachment 2 of the announcement as posted on the CDC Web site).

Measurable outcomes of this research study will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC), described as a priority in the NCIPC Research Agenda: To monitor and detect fatal and non-fatal injuries.

#### C. Eligible Applicants

Applications may be submitted by: Public nonprofit organizations, private nonprofit organizations, universities, colleges, technical schools, research institutions, hospitals, managed care organizations, community-based organizations, faith-based organizations, federally recognized Indian tribal governments, Indian tribes, Indian tribal organizations, State and local governments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.)

**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.

#### D. Funding

##### *Availability of Funds*

Approximately \$500,000 is available in FY 2003 to fund one award. It is expected that the award will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project period of up to four years. The funding estimate 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.

##### *Use of Funds*

Funds awarded may not be used to supplant funds available from other sources to the recipient to conduct similar activities. Funds are not to be used for construction purposes, the rental of office space, or for the purchase or rental of furniture. Eligible applicants may enter into contracts including consortia agreements as necessary to meet the requirements of the program and strengthen the overall application.

#### *Recipient Financial Participation*

Matching funds are not required for this program.

#### E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and CDC will be responsible for the activities listed in 2. CDC Activities.

##### *1. Recipient Activities*

a. With assistance from the CDC, prepare a detailed research protocol for Institutional Review Board (IRB) approval by all cooperating institutions participating in the study. The protocol shall include but is not limited to the following: Detailed description of methods for selecting the study sample, recruitment and enrollment methods, the informed consent process and consent forms, study instruments including questionnaires if applicable, methods for data handling and storage including methods for ensuring participant confidentiality, data analysis, and plans for data dissemination.

b. Develop a detailed operations manual and other manuals documenting study methods.

c. Train study personnel.

d. Recruit and enroll study participants.

e. Collect and enter the data.

f. Analyze and interpret the data.

g. Report study findings, including in peer-reviewed publication(s).

##### *2. CDC Activities*

a. Assist in effective study planning and management.

b. CDC will provide critical guidance related to the study design, including the case definition for mild traumatic brain injury and selection of the study population.

c. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

d. CDC will provide guidance about protocol format and content as well as scientific and human subjects considerations.

e. CDC staff will collaborate in the analysis of data.

f. CDC will collaborate in the reporting of findings by participating as co-authors in the preparation of peer-reviewed publications.

g. CDC staff will convene routine conference calls with the recipient and

conduct a site visit annually or as needed to review progress.

## F. Content

### *Letter of Intent (LOI)*

A LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The LOI should be no more than two pages, double-spaced, printed on one side, with one-inch margins, and unrounded 12-point Times Roman font. Your LOI will be used to determine level of interest in the announcement. The LOI should include the following information:

1. Program Announcement Number 03106.
2. Name and address of institution.
3. Name and telephone number of the principal investigator.
4. A summary of the key research hypotheses, study design and proposed methods you intend to use if awarded funding.
5. A brief description of proposed collaborations with health departments or other entities, if applicable.

### *Applications*

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed so it is important to follow them in laying out your program plan. The narrative should be no more than 30 (8½" x 11") double-spaced pages, printed on one side, with one inch margins on all four sides, and unrounded 12-point Times Roman font, and a page number at the bottom of each page. Applications with more than 30 pages will be returned and not reviewed. Please provide only attachments or appendices that are directly relevant to this request for funding. Include sample forms and data collection instruments. The budget and attachments/appendices, including letters of support, are not included in the count for the 30-page limit. All pages, including appendices, must be numbered sequentially.

Applications should follow the PHS-398 (Rev. 5/2001) application and Errata sheet. The PHS 398 Errata sheet is posted on the CDC web site. The narrative should contain the following information in the order presented:

1. Abstract (1 page recommended).
- a. Provide a brief abstract of the proposed study including key research hypotheses, study design and proposed methods.

- b. The abstract must reflect the study's focus and the length of the project period (maximum of four years) for which assistance is being requested (see "Availability of Funds"). Amount of federal assistance requested.

2. Proposal Narrative

- a. Background, including literature review and justification of the need for the research.

- b. Goals, objectives, and timeline for completion.

- c. Study design and methods, including hypotheses to be tested, proposed study population and methods for selection of the study sample, proposed time post-injury for assessing participants, case definition for mild traumatic brain injury, existing measure(s) to be validated or proposed methods for development of new measure(s), methods for assessing the reliability and validity of measure(s), and data analysis methods.

- d. Study management and staffing, including institutional resources, investigator and staff qualifications and experience.

- e. Proposed methods to evaluate the attainment of objectives.

3. Budget Narrative

4. Human Subjects

5. Appendices—which may include letters of commitment from key collaborators, resumes of key staff, brief summary reports of analyses of TBI surveillance data.

## G. Submission and Deadline

### *Letter of Intent (LOI) Submission*

The LOI must be received by June 17, 2003. Submit the LOI, on the applicant's letterhead, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### *Application Forms*

Submit the signed original and five copies of PHS 398 (OMB Number 0925-0001). Adhere to the instructions on the Errata Instruction Sheet for PHS 398. Forms are available 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) at: 770-488-2700. Application forms can be mailed to you.

### *Submission Date, Time, and Address*

The application must be received by 4 p.m. Eastern Time July 2, 2003. Submit the application to: Technical

Information Management-PA 03106, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

### *CDC Acknowledgment of Application Receipt*

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

### *Deadline*

Letters of Intent and applications shall be considered as meeting the deadline if they are received before 4:00 Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, natural or manmade disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above requirements will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

## H. Evaluation Criteria

### *Application*

Applications which are complete and responsive may be subjected to a preliminary evaluation (streamline review) by a peer review committee, the Special Emphasis Panel (SEP), to determine if the application is of sufficient and scientific merit to warrant further review by the SEP. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. A dual review process will evaluate applications that are complete and responsive.

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee SEP, recommendations by the secondary review committee of the Science and Program Review Subcommittee of the Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

1. The primary review will be a peer review conducted by the SEP. A committee of reviewers with appropriate expertise will review all applications for scientific merit using current National Institutes of Health (NIH) criteria (a scoring system of 100–500 points) to evaluate the methods and scientific quality of the application. All categories are of equal importance, however, the application does not need to be strong in all categories to be judged likely to have a major scientific impact.

Factors to be considered will include:

a. Significance—Does this study address an important problem? Does the applicant justify the present proposal using existing scientific knowledge? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

b. Approach—Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant describe the specific questions this research is intended to address? Does the applicant describe how relevant behavioral theories will be applied to encourage the proposed activities? Does the applicant describe the hypotheses to be tested, the specific study goals, measurable objectives, and outcomes? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included? Does the applicant provide a detailed time-line for the first year of the study as well as a projected time-line for the subsequent years?

Does the applicant describe methods for selecting the study population and study sample, timing of assessments post-injury, and identifying participants (case definition for MTBI) measure(s) or validating existing measure(s) of outcomes of MTBI, and for assessing the reliability and validity of those measures?

Are there adequate plans for data collection and data management including security of data, assurance of participant confidentiality, data entry, editing, and quality assurance procedures? Is there a statistical analysis plan appropriate for the study design?

c. Innovation—Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or

develop new methodologies or technologies?

d. Investigator—Is the principal investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting TBI-related research? Does the applicant document capacity to accomplish the proposed study as demonstrated by relevant past or current experience conducting research on TBI outcomes and/or developing and validating outcome measures?

e. Environment—Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Is there evidence of institutional support? Does the applicant describe the personnel and study collaborators needed to accomplish the proposed activities? Does the applicant provide evidence that the study personnel have the expertise and capacity to accomplish the proposed activities and to provide appropriate scientific oversight necessary to fulfill study goals and objectives?

Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement? Is there evidence of the experience and capacity for all key staff members including CVs and position descriptions?

f. Study Samples—Are the samples rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

g. Ethical Issues—What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, (e.g., suspected child abuse)?

Does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection

against risks is so inadequate as to make the entire application unacceptable.

Does the application adequately address 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.

h. Dissemination—What plans have been articulated for disseminating findings?

i. Measures of Effectiveness—The Peer Review Panel shall assure that measures set forth in the application are in accordance with CDC's performance plans. How adequately has the applicant addressed these measures?

j. Budget—The SEP will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

2. The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of the ACIPC. ACIPC Federal agency experts will be invited to attend the secondary review and will receive modified briefing books (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). ACIPC Federal agency experts will be encouraged to participate in deliberations when applications address overlapping areas of research interest so that unwarranted duplication in federally funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the ACIPC Federal agency experts to assure that research priorities of the announcement are understood and to provide background regarding current research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered

would be the same as those considered by the SPRS.

The Subcommittee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally funded research does not occur. The secondary review Subcommittee has the latitude to recommend to the NCIPC Director, to reach over better-ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

- a. The results of the primary review including the application's priority score as the primary factor in the selection process.
- b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.
- c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010," the Institute of Medicine report, "Reducing the Burden of Injury," and the NCIPC "Injury Research Agenda."
- d. Budgetary considerations including the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

## I. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress reports, 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.
  2. Financial status reports, 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.
- Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC Web site.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-13 Prohibition on Use of CDC funds for Certain Gun Control Activities
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-21 Small, Minority, and Women-Owned Business
- AR-22 Research Integrity

Executive order 12372 does not apply to this program.

### J. Where To Obtain Additional Information

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

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Wanda Allison, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2645, E-mail address: [wallison@cdc.gov](mailto:wallison@cdc.gov).

For business management and budget assistance in the territories, contact: Angelia Hill, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770) 488-2785, E-mail address: [aph8@cdc.gov](mailto:aph8@cdc.gov).

For program technical assistance, contact: Stacy Harper, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F-41, Atlanta, GA 30341-3724, Telephone number (770) 488-4031, E-mail address: [slharper@cdc.gov](mailto:slharper@cdc.gov).

Dated: May 23, 2003.

**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 Disease Control and Prevention

[Program Announcement 03057]

### Cooperative Agreement for a National Poison Prevention and Control Program; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for a national poison prevention and control program was published in the **Federal Register** on May 7, 2003, Volume 68, Number 88, on pages 24483-24485. The notice is amended as follows: On page 24483, in the second column, section E. Program Requirements, item 1(a) should read: Develop a plan to improve the current national toxics surveillance system, with a focus on improvement of data collection and coding. Enhance real time data collection and aberration detection capabilities of TESS.

Dated: May 23, 2003.

**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 Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Active Surveillance for Pertussis—Surveillance for Vaccine Preventable Disease as a Foundation for Evaluating the Effectiveness and Impact of an Adolescent/Adult Pertussis Immunization Program and for Evaluating the Feasibility of a Pediatric Hospital-Based Sentinel Surveillance Network for Vaccine Preventable Diseases, Program Announcement #03101 and Solicitation 2003-N-0837

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease