http://www.cdc.gov/ncipc/osp/ sharing_policy.htm

VI.3. Reporting

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

following reports:

- 1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) 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. Measures of effectiveness.
- f. Additional requested information.
- 2. Financial status 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 Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For scientific/research issues, contact: Karin Mack, Ph.D., National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy NE., Mailstop K–63, Atlanta, GA 30341. Telephone: 770–488–4389. E-mail: KMack@cdc.gov.

For questions about peer review, contact: Gwendolyn Cattledge, PhD, Scientific Review Administrator, Associate Director for Extramural Research, National Center for Injury Prevention and Control Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02. Telephone: 770–488–1430. E-mail: gxc8@cdc.gov.

For financial, grants management, or budget assistance, contact: James Masone, Grants Management Specialist, CDC Procurement and Grants Office,2920 Brandywine Road, Atlanta, GA 30341. E-mail: JMasone@cdc.gov.

VIII. Other Information

This and other CDC funding opportunity announcements can be

found on the CDC web site, Internet address: www.cdc.gov. Click on "Funding" then "Grants and Cooperative Agreements."

William P. Nichols,

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

[FR Doc. 04–24715 Filed 11–5–04; 8:45 am] BILLING CODE 4163–18–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Injury Surveillance and Prevention Program

Announcement Type: New. Funding Opportunity Number: CE05– 027.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: December 8, 2004.

Application Deadline: February 7, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under sections 391(a) and 301(a) of the Public Health Service Act (PHS Act) and [42 U.S.C. 241(a) and 280b(a)], as amended.

Purpose: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2005 funds for a cooperative agreement program for the development, enhancement, and integration of injury prevention and control and surveillance programs. The purpose of this program is to enable State public health agencies to develop or strengthen their organizational focus related to the prevention and control of injuries and to develop or strengthen their injury surveillance programs, particularly those with a focus on traumatic brain injury (TBI). This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

This announcement incorporates funding guidance for the following four components: Part A—the Integrated Core Injury Prevention and Control (ICIPC) Program, Part B—the Traumatic Brain Injury Extended Surveillance (TBIES) Program, Part C—the Traumatic Brain Injury Emergency Department (TBIED) Surveillance Program and Part D—the Traumatic Brain Injury Service Linkage (TBISL) Program. All States/territories must qualify and be recommended for funding for Part A (ICIPC) in order to be eligible for Part B

(TBIES), Part C (TBIED) or Part D (TBISL). The ICIPC component supports the planning, implementation and integration of comprehensive injury prevention and control activities with basic injury surveillance activities. CDC defines injury program integration as a coordinated approach to reducing the incidence, morbidity and mortality of injury through surveillance and prevention efforts. The TBIES component supports efforts to provide expanded information on the incidence of traumatic brain injury. The TBIED component supports efforts to provide information on the incidence of mild traumatic brain injury treated in the emergency department. The TBISL component supports efforts to link individuals with traumatic brain injury to information about services.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for Injury Prevention and Control:

- 1. Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence.
- 2. Monitor and detect fatal and non-fatal injuries.

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: http://www.cdc.gov/od/ads/opspoll1.htm

Activities

Part A: The Integrated Core Injury Prevention and Control (ICIPC) Program

In conducting activities to achieve the purpose of Part A of this program, the recipient will be responsible for incorporating the core components of a model State injury prevention program as outlined in the STIPDA: Safe States— 2003 Edition. For a downloadable version of this document, please see the STIPDA Web site at the following Internet address: http://www.stipda.org/ safestates.htm.Activities to be followed related to this requirement are described below. CDC has developed performance measures to evaluate recipients' progress in meeting ICIPC requirements. These performance measures are listed following each associated recipient activity. Activities are as follows:

- Building a Solid Infrastructure for Injury Prevention and Control.
- Enhance comprehensive injury prevention and control infrastructure by acquiring key staff and associated resources to

- coordinate and integrate comprehensive injury prevention and control efforts with statewide injury surveillance efforts. Performance will be measured by the extent to which the program has:
- Established the infrastructure for ICIPC including staff and other resources.
- Where appropriate, established written inter-agency/organizational agreements (e.g. Memoranda of Understanding) related to the roles, duties and responsibilities of shared staff.
- O Mobilize support and build partnerships by identifying, contacting and inviting potential key private, professional, voluntary and nonprofit injury prevention and control organizations, injury care providers, policymakers, consumers, payers, media, State and Federal agencies, surveillance, research and academic institutions, and others to become members of a new or existing State/territory-wide Injury Community Planning Group (ICPG). The role of the ICPG may include, but should not be limited to: Participation of members on injury prevention and control boards and commissions, providing information on the effectiveness of existing State policies related to injury prevention and control, and reviewing surveillance data to help identify and prioritize injury problems within the State. Performance will be measured by the extent to which the program and ICPG has developed and sought guidance from coalitions and partners, both within and outside of the organization and sustained these partnerships as ongoing entities by such activities as:
- Generating support and resources or securing funding to support Integrated Core Injury Prevention and Control Program (ICIPC) activities.
- Establishing written responsibilities for the ICPG (e.g., in a mission statement or scope of work).
- Supporting the ICPG process by providing funding and resources.
- Assuring the ICPG has access to current information about injury prevention and control.
- Conducting one ICPG injury prevention symposium per budget year to develop specific marketing injury strategies for the comprehensive injury prevention plan. The symposium should include, but not be limited to:

- Regional/statewide representatives of key governmental and non-governmental agencies; media outlets; HMOs/MCOs; hospital/trauma/medical centers; state athletic associations; medical/professional organizations/associations and other stakeholders or gatekeepers.
- Develop a State injury prevention and control plan, or where appropriate, conduct a systematic evaluation and update of the existing injury prevention and control plan. In each case, the recipient should work with their ICPG to assure that their plan includes prioritized measurable goals and objectives with timeframes, and identifies implementing organizations for priority plan strategies. Performance will be measured by the extent to which the plan reflects that the program:
- Used data to describe the epidemiology of the burden of injury in the State/territory.
- Évaluated the epidemiologic data to determine the critical target areas for injury prevention and control activities.
- Established priorities and chosen appropriate evidence-based intervention strategies.
- Identified implementing organizations for priority plan strategies.
- Developed objective/quantitative measures of effectiveness that will demonstrate accomplishment of program goals and objectives and measure intended outcomes.
- Collaborate and coordinate with your State's Office of Terrorism Preparedness and Emergency Response (or its equivalent) to assure their participation in the ICPG and in the development/ update of the State injury prevention and control plan. Performance will be measured by the extent to which the program secures memorandums of understanding (MOU) documenting this collaboration.

- and centralized electronic vital statistics data sets [see eligibility information (i.e., Special Requirements) for allowable exceptions]. Performance will be measured based upon the extent to which the program has demonstrated that it:
- Used available data to inform the injury prevention and control planning process.
- Used available data to evaluate progress toward meeting the core goals and objectives of the state/territory injury prevention and control program.
- Promoted and facilitated the use of injury data to meet the needs of injury prevention and control groups and service agencies (e.g., HRSA).
- Participated in the Multi-State Injury Indicator Report.
- States/Territories must submit an annual injury data report produced for use in their own state/territory and for submission to CDC. This report shall be consistent with CDC's current recommendations for Injury Indicator Surveillance (see Appendix 1 for detailed methodology). In addition, this report shall include completed tables with aggregated numbers and rates categorized by sex, age group, and external cause for All-injury deaths and hospitalizations, TBI related deaths and hospitalizations, drowning related deaths and hospitalizations, fire related deaths and hospitalizations, motor vehicle related deaths and hospitalizations, poisoning related deaths and hospitalizations, firearm related deaths and hospitalizations, suicide related deaths and hospitalizations, and homicides. The report shall include a written interpretation of the injury data in a format suitable for dissemination within the State/ territory and shall include a focus on priority areas identified by the State/territory and a brief analysis of TBI in the state/territory. Performance will be measured by the extent to which the program has:
- Incorporated CDC's recommendations for data completeness, timeliness, and quality.
- Compliance will be determined based upon the successful submission of required annual reports and the completeness of the submitted spreadsheet tables (spreadsheet format will be supplied by CDC).
- The first annual injury data report

should include data from 01/01/2004–12/31/2004. The report must be received as an attachment to the annual report (due October 31). For example, CDC should receive the first report using 2004 data no later than October 31, 2006. Subsequent annual reports will follow the same pattern.

- Implement, and Evaluate Interventions
 - Implement priorities as established by the State/territory comprehensive injury prevention and control plan, which provides a framework for action to reduce the burden of injury in the State/ territory. Performance will be measured by the extent to which the program has:

 Identified interventions focused on priorities outlined in the state/ territory wide injury prevention and control plan.

■ Identified and collaborated with influential and appropriate partners who are able to implement and support injury prevention and control plan activities/strategies.

 Continuously evaluated and monitored its own process and the outcomes of the ICIPC plan, its objectives and activities.

- Use surveillance findings to inform and guide State/territory injury prevention and control activities, including the ICIPC where applicable. Performance will be measured by the extent to which the program has:
- Used surveillance findings to guide injury prevention and control activities.
- Used surveillance findings to evaluate the effectiveness of intervention programs.
- States/Territories funded under this cooperative agreement must send representation to the annual CDC sponsored grantees meeting.

Part B: Traumatic Brain Injury Extended Surveillance (TBIES) Program

In conducting activities to achieve the purpose of Part B of this program, the recipients will be responsible for conducting all of the activities of Part A as well as the activities described below. CDC has developed performance measures to evaluate recipients' progress in meeting TBIES requirements. These performance measures are listed following each associated recipient activity. Activities are as follows:

 TBI Basic Electronic Surveillance
 Conduct centralized statewide electronic surveillance of TBI, consistent with standard definitions and methods for TBI surveillance described in the current Annual Data Submission Standards for Central Nervous System (CNS) Injury Surveillance. For a downloadable version of this document, please see the CDC Web site at the following Internet address: http://www.cdc.gov/doc.do/id/0900f3ec80145eec.Performance will be measured by the extent to which the program has:

- Used centralized statewide electronic hospital discharge and vital statistics databases for case identification.
- Linked and unduplicated data obtained from centralized statewide electronic hospital discharge and vital statistics databases, including data elements that describe diagnosis, demographics, external cause, and discharge disposition.
- TBI Extended Medical Record Surveillance
 - Annually review the medical records of a representative sample of reported hospitalized cases to obtain data consistent with standard definitions for the expanded TBI dataset described in the current Central Nervous System Injury Surveillance Data Submission Standards. Performance will be measured by the extent to which the program has:
 - Complied with CDC's standards for data completeness and quality. Compliance will be determined based on an evaluation of data submitted to CDC's National Center for Injury Prevention and Control. The first annual data submission should include data from 01/01/ 2004-12/31/2004. The data must be received by CDC as an attachment to the annual report. For example, CDC should receive the first data submission using 2004 data no later than October 31, 2006. Subsequent annual data submissions will follow the same pattern.
 - Ouring years two through five collect additional information on 10–15 TBI data elements related to a topic of emerging public health importance. CDC and all grantees participating in extended surveillance will jointly decide upon topic areas during year 1. Performance will be measured by the extent to which the program has:
 - Complied with data collection efforts mutually agreed upon by CDC and the program. Compliance will be determined based on an evaluation of data submitted to

CDC's National Center for Injury Prevention and Control.

Analysis and Reporting

Analyze and interpret collected data and prepare an annual report suitable for dissemination within the State/territory either separately or within the All-injury report described in Part A. Performance will be measured by the extent to which the program:

Successfully disseminates the report within the State/territory and submits the report to CDC's NCIPC.

- Generate an annual summary report documenting methodological and other issues related to conducting extended surveillance to include programmatic lessons learned, strengths and limitations of the data, usefulness of the data for State/territory injury prevention and control planning, etc. This information will be used to expand and improve the content of CDC's "Annual Data Submission Standards, Central Nervous System Injury Surveillance." Performance will be measured by the extent to which the program:
- Successfully submits the report to CDC's National Center for Injury Prevention and Control.

Part C: Traumatic Brain Injury Emergency Department Surveillance (TBIED) Program

In conducting activities to achieve the purpose of Part C of this program, the recipients will be responsible for conducting all the activities of Part A as well as the activities described below. CDC has developed performance measures to evaluate recipients' progress in meeting TBIED requirements. These performance measures are listed following each associated recipient activity. Activities are as follows:

- Basic Electronic Surveillance
- Conduct centralized statewide electronic emergency department (ED) surveillance of TBI, consistent with standard definitions and methods for TBI surveillance described in the current Central Nervous System Injury Surveillance Data Submission Standards. Performance will be measured by the extent to which the program has:
- Used centralized statewide electronic ED databases for case identification.
- Linked and unduplicated data obtained from centralized statewide electronic ED databases with centralized electronic hospital discharge data and centralized

- electronic vital statistics data. Emergency Department Surveillance
- Annually review the medical records of a representative sample of reported cases to obtain data consistent with standard definitions for the extended TBI dataset described in the current Central Nervous System Injury Surveillance Data Submission Standards. In addition to the evaluation measures included in the current Central Nervous System Injury Surveillance Data Submission Standards, perform an annual evaluation of sensitivity to include at a minimum a qualitative assessment of the data sources (e.g., number and proportion of EDs participating in the State). Performance will be measured by the extent to which the program has:
- Complied with CDC's standards for data completeness and quality. Compliance will be determined based on an evaluation of data submitted to CDC's National Center for Injury Prevention and Control. The first annual data submission should include data from 01/01/ 2004-12/31/2004. The data must be received by CDC as an attachment to the annual report. For example, CDC should receive the first data submission using 2004 data no later than October 31, 2006. Subsequent annual data submissions will follow the same pattern.

Analysis and Reporting

Analyze and interpret collected data and prepare an annual report suitable for dissemination within the State/territory either separately or within the All-injury report described in Part A. Performance will be measured by the extent to which the program:

Successfully disseminates the report within the State/territory and submits the report to CDC's National Center for Injury Prevention and Control.

- Generate an annual summary report documenting methodological and other issues related to conducting ED surveillance to include programmatic lessons learned, strengths and limitations of the data, usefulness of the data for State/territory injury prevention and control planning, etc. This information will be used to expand and improve the content of CDC's 'Guidelines for ED Surveillance.' Performance will be measured by the extent to which the program:
- Successfully submits the report to CDC's National Center for Injury Prevention and Control.

Part D: Traumatic Brain Injury Service Linkage (TBISL) Program

In conducting activities to achieve the purpose of Part D of this program, the recipients will be responsible for conducting all of the activities of Part A as well as the activities described below. CDC has developed performance measures to evaluate recipients' progress in meeting TBISL requirements. These performance measures are listed following associated recipient activities. Activities are as follows:

· Feasibility assessment

- In year one, conduct an assessment of the feasibility of (a) obtaining from the State/territory TBI surveillance system, personal identifying and contact information for a sample of persons hospitalized with TBI and (b) using that information to provide those individuals with information about available services in their State. Performance will be measured by the extent to which the program:
- Submits a report summarizing the results of the feasibility assessment. This assessment should identify potential partners for linkage activities and discuss the pros and cons of differing linkage strategies within the State/territory. Information to be collected will be decided upon in collaboration with CDC. The feasibility assessment report must be submitted as an attachment to the Year one interim report (due six months after the beginning of the budget period).
- In year one, develop and submit a plan for linkage implementation based on results of the feasibility study. The plan for linkage implementation must be submitted as part of the Year one annual report due October 31, 2006. Performance will be measured by the extent to which the plan:
- Describes the populations to be linked, including justification for their selection.
- Clearly describes the methods for proposed linkage activities including a process for identifying and linking persons to information about services within an

appropriate timeframe post injury.

■ Identifies partners with whom they will collaborate in conducting linkage activities and from whom they have received letters of support.

Implementation

 İn year two, States must implement proposed linkage activity(ies) as a pilot and prepare a report, which

includes findings/results and lessons learned. The report must be submitted as an attachment to the Year two annual report due October 31, 2007. Performance will be measured by the extent to which the program:

■ Has successfully implemented pilot activities and has summarized their actions in a report to the CDC's National Center for Injury

Prevention and Control.

- In years three through five, States/ territories must conduct the linkage activity(ies), and prepare an annual report summarizing the activity including; findings/results, lessons learned, and implications/ recommendations for future activities in this and in other States/ territories. The report must be submitted as an attachment to the Year three to five annual reports, due October 31st. Performance will be measured by the extent to which the program has:
- Continuously evaluated and monitored its own process, objectives and activities.
- Developed and monitored measures of effectiveness for its proposed activities.
- Successfully submitted required reports.

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

CDC Activities for this program are as follows:

Part A

- · Assist with the exchange of information and collaboration among
- Provide recipients with relevant research findings and public health recommendations related to comprehensive injury prevention and control.
- Provide ongoing guidance, consultation, and technical assistance in conducting recipient activities.
- Assist with the identification of national injury prevention and control campaigns and materials that can be integrated into comprehensive injury prevention and control programs.
- Provide recipients with instructions and spreadsheets for calculating annual injury indicator data.

Part B

- · Provide ongoing guidance, consultation, and technical assistance in conducting recipient activities.
- Collaborate with grantees to establish standards for data completeness, timeliness, and quality,

and to promote the use of TBI data to support injury prevention and control efforts.

• Receive, assess, aggregate and disseminate TBI data from grantees.

Part C

- Provide ongoing guidance, consultation, and technical assistance in conducting recipient activities.
- Collaborate with grantees to establish standards for data completeness, timeliness, and quality, and to promote the use of TBI data to support injury prevention and control efforts.
- Receive, assess, aggregate and disseminate TBI data from grantees.

Part D

- Assist with the exchange of information and collaboration among recipients.
- Provide ongoing guidance, consultation, and technical assistance in conducting recipient activities.

II. Award Information

Type of Award: Cooperative Agreement.

Budgets should be prepared for Parts A, B, C, & D separately. In the application packet, you should list each Part's budget amount in separate columns on the SF424 (*i.e.*, Part A in column 1, Part B in column 2, Part C in column 3 and Part D in column 4). Details on this form and instructions for submitting an application are provided in the "Application and Submission" section. CDC involvement in this program is listed in the Activities Section above.

Part A (ICIPC)

Fiscal Year Funds: 2005. Approximate Total Funding Available: \$4,750,000.

Approximate Number of Awards: 33. Approximate Funding per Award: \$144,000.

Floor of Award Range: None. Ceiling of Award Range: \$150,000.

Part B (TBIES)

Fiscal Year Funds: 2005. Approximate Total Funding Available: \$440,000.

Approximate Number of Awards:

Approximate Funding per Award: \$110,000.

Floor of Award Range: None. Ceiling of Award Range: \$110,000.

Part C (TBIED)

Fiscal Year Funds: 2005. Approximate Total Funding Available: \$300,000. Approximate Number of Awards: Two.

Approximate Funding per Award: \$150,000.

Floor of Award Range: None. Ceiling of Award Range: \$150,000.

Part D (TBISL)

Fiscal Year Funds: 2005. Approximate Total Funding Available: \$150,000.

Approximate Number of Awards: Three.

Approximate Funding per Award: \$50,000.

Floor of Award Range: None. Ceiling of Award Range: \$50,000.

If you request a funding amount greater than the ceiling of award range per Part, your application will not be considered eligible and not forwarded for review. This ceiling of award range per part is for the first 12-month budget period and includes both indirect and direct costs. If considered ineligible, you will be notified in writing by NCIPC prior to start date of the award.

Anticipated Award Start Date: August 1, 2005.

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 health departments of States and territories or their bona fide agents, this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. A Bona Fide Agent is an agency/ organization identified by the State/ territory as eligible to submit an application under the State/territory eligibility in lieu of a State/territory application. If you are applying as a bona fide agent of a State/territory, you must provide documentation of your status. Place this documentation behind the first page of your application form.

Special Requirements: 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.

- All States/territories should demonstrate the ability to access a centralized electronic hospital discharge data set. States/Territories unable to access centralized electronic hospital discharge data sets must demonstrate the ability to access an alternate centralized electronic data set that is representative of the State/territory hospitals. As an appendix to this application include a summary of current (i.e., 2001, 2002 or most current morbidity data analyzed by age, sex and cause).
- All States/territories must demonstrate the ability to access centralized electronic vital statistics data sets. As an appendix to this application include a summary of current (*i.e.*, 2001, 2002 or most current mortality data analyzed by age, sex and cause).
- States/territories previously funded under program announcement numbers 00119, 02207 and 99136 must submit a State/territory-wide injury prevention and control plan as an appendix to this application.
- States/Territories must maintain an active Injury Community Planning Group (ICPG) the ICPG shall be responsible for developing/enhancing injury prevention and control plan and marketing strategy to promote the vision and values of the Integrated Core Injury Prevention and Control Program.
- All States/territories must qualify and be recommended for funding for Part A (ICIPC) in order to be eligible for Part B (TBIES), Part C (TBIED) or Part D (TBISL). Note: For this reason, the CDC review panel will only consider Parts B, C and D of the applications reviewed, approved and funded for Part A
- States/Territories applying for Part C (TBIED) must demonstrate the ability to access centralized electronic emergency department discharge data sets.
- States/Territories applying for Part D (TBISL) who propose direct patient contact must have legal authority to contact individuals identified by surveillance activities. In order to demonstrate legal authority applicants must submit both of the following as an appendix to the application: A copy of the supporting legislation/regulation and a letter from the appropriate health department official (e.g. attorney or health officer) certifying that the applicant will have access to personal identifying information of TBI cases for the purposes of the linkage activities outlined in this RFA.

• 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.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form CDC 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: 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 submit a LOI if you intend to apply for one or more parts of 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 written in the following format:

- Maximum number of pages: Two.
- Font size: 12-point unreduced.
- 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.

Your LOI must contain the following information:

- Number and title of this Program Announcement (PA#).
- Identification of Part(s) for which you intend to apply.

Application: You are required to send a cover letter that summarizes which Parts you are applying for, dollar amounts, and point of contact information. Ensure that each part of the application and section are properly labeled and include page numbers. A detailed budget and narrative justification must be provided. 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.You must include a

table of contents. You must submit a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: Part A-25; Part B-15; Part C-15; Part D-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 unreduced.
 - 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 wav.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Part A: Executive summary, state of need, goals and objectives, methods and staffing, evaluation, collaboration, and budget and justification (appendices, budget and justification will not be counted in the stated page limit).
- Part B: Executive summary, review of literature and statement of need, methods and activities, capacity to conduct TBI Surveillance, goals and objectives, management and staffing, evaluation, and budget and justification (appendices, budget and justification will not be counted in the stated page limit).
- Part C: Executive summary, review of literature and statement of need, methods and activities, capacity to conduct TBI ED surveillance, goals and objectives, management and staffing, evaluation, and budget and justification (appendices, budget and justification will not be counted in the stated page limit).
- Part D: Executive summary, review of literature and statement of need, methods and activities, capacity, goals and objectives, management and staffing, evaluation, collaboration and budget and justification (appendices, budget and justification will not be counted in the stated page limit).

 Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit.

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 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/pubcommt.htm. 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: December 8, 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: February 7, 2005.

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 submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission 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 submission as having been received by the deadline.

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

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or 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 submission deadline. This will allow time for submissions 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:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.
- Federal funds awarded under this announcement may not be used to offset existing, State funded projects.

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

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Angela Marr, 4770 Buford Hwy., NE., M.S. F-41, Atlanta, GA 30341-3724. Tel: (770) 488-1428.Fax: (770) 488-4338. E-mail: amarr@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—#CE05-027, 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

Applicants 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:

Part A (ICIPC)

Each application will be evaluated and scored individually by an objective review panel. Evaluation and scoring for Part A will be conducted according to the following criteria:

• Need for an Integrated Core Injury Prevention and Control Program (30 points)

- Did the applicant describe the need for an Integrated Core Injury Prevention and Control Program and the nature of any current injury prevention and control or surveillance programs in their State?
- O Did the applicant describe the current level of agency/inter-agency resources dedicated to injury activities and how additional funding will contribute to efforts to initiate or improve existing or planned injury surveillance activities?
- O Did the applicant provide evidence of a current or existing injury prevention and control plan to develop or enhance its injury prevention and control or surveillance system?

Methods and Staffing (30 points)

- Did the applicant provide a detailed description of how staffing resources (including epidemiological resources) will be allocated and used to accomplish each objective and overall program goals?
- O Did the application include the designation of a coordinator with the responsibility for coordinating Integrated Core Injury Prevention and Control Program activities?
- O Did the applicant provide a reasonable and complete timeline for implementing and completing all activities and objectives?
- Did the application provide a description of the roles of each unit, organization, or agency, as well as evidence of coordination, supervision, and degree of commitment (e.g., time, in-kind, financial) of staff, organizations, and agencies involved in Integrated Core Injury Prevention and Control Program activities?
- O Did the application provide evidence of access to or assignment of epidemiological expertise for performing routine data review and analysis activities and providing technical advice and consultation?
- Did the applicant provide evidence of intra-agency memoranda of understanding outlining; roles, duties, responsibilities and travel authorization for shared staff where

appropriate to travel to CDC sponsored meetings?

Evaluation (20 points)

Is the proposed evaluation system detailed? Does it address the goals and objectives of the program? Will it effectively evaluate program progress, effectiveness, and impact?

- O Does the application demonstrate the availability of potential data sources for evaluation purposes? Does it outline methods to evaluate the data sources? Does it document the availability of staff with the appropriate expertise, experience and capacity to perform program evaluation?
- Does the application present a feasible plan for reporting evaluation results and for using evaluation information for programmatic decisions and

continuous program improvement? • Goals and Objectives (10 points)

ODid the applicant include goals that are relevant to the purpose of the proposal and feasible to accomplish during the project period? Are the goals specific and measurable?

Did the applicant include objectives that are feasible to accomplish during the budget period? Are the activities outlined necessary to accomplish the purpose of the proposal?

Collaboration (10 points)

• Has the applicant provided adequate information to assess the relationships between the program and other organizations, agencies, and health department units that will relate to the program or conduct related activities?

O Has the applicant provided a clear and adequate description of appropriate membership and roles of an Injury Community Planning

Group?

Did the applicant provide evidence of intra-agency memoranda of understanding outlining roles, duties, responsibilities and travel authorization where appropriate to travel to CDC sponsored meetings?

• Budget and Justification (not scored)

- Has the applicant provided a detailed budget and narrative justification consistent with the stated objectives and planned program activities?
- Has the applicant provided a budget to include funds for attending the annual grantees meeting?

Part B (TBIES)

Each application will be evaluated and scored individually by an objective review panel. All applications will be evaluated and scored first for Part A and subsequently, where applicable, for Part B.

Evaluations and scoring for Part B will be conducted according to the following criteria:

- Methods and Activities: (35 points)
- Can the methods and activities achieve the proposed objectives, consistent with the purposes of this announcement? Did the applicant propose appropriate methods and activities to collect and analyze optional data consistent with the Program Requirements for Part B, including sampling methods and proposed staffing?

 Capacity to conduct TBI surveillance: (20 points)

- Old the applicant demonstrate authority to collect and maintain necessary TBI surveillance data consistent with the current CDC Central Nervous System Injury Surveillance Data Submission Standards, with demonstrated timeliness of case ascertainment, completeness of case ascertainment, and ability to analyze data? Did the applicant demonstrate appropriate existing capacity to collect and analyze optional data (e.g., describing TBI severity, circumstances, and early outcome) from a representative sample of cases reported to the TBI surveillance system? If previously funded under PA #01030, did the applicant provide evidence of successful TBI surveillance activities, including:
- A summary of current (*i.e.*, 2001, 2002 or most current) TBI morbidity and mortality data analyzed by age, sex. and cause:
- An evaluation of TBI surveillance data quality (e.g., predictive value positive, completeness, timeliness);
- Letter(s) from CDC indicating successful submission of annual datasets for 2000, 2001 and 2002?

If not previously funded under PA#01030, did the applicant provide evidence of successful TBI surveillance capacity, including:

- A summary of current (*i.e.*, 2001, 2002, or most current) TBI morbidity and mortality data analyzed by age, sex, and cause;
- An evaluation of TBI surveillance data quality (e.g., predictive value positive, completeness, timeliness).
- Management and Staffing: (20 points)
 Does the staffing plan indicate the applicant's ability to carry out the objectives of the program?
 Considerations include: organizational structure, staff qualifications, experience, degree of

- stability maintaining current staff in critical positions, identified training needs or plan, and job descriptions and curricula vitae for both proposed and current staff. Does the applicant plan to coordinate activities with any other injury surveillance, prevention, and control programs or activities in the applicant's organizations?
- Goals and Objectives: (10 points)
 Are the objectives specific, achievable, practical, measurable, time-linked, and consistent with the overall purposes described in this announcement?

• Evaluation: (10 points)

 Did the applicant include plans to evaluate the attainment of proposed objectives, including plans to evaluate the sensitivity and predictive value positive of case ascertainment and the completeness and quality of data?

 Review of Literature and Statement of Need: (5 points)

 Did the applicant review key literature relevant to the proposed project, and did the applicant describe needs within the jurisdiction to which the application is responsive?

Budget and Justification: (not scored)
 Are the budget reasonable, clearly justified, and consistent with stated objectives and proposed activities?

 Has the applicant provided a budget to include funds for attending the annual grantees meeting?

Part C (TBIED)

Each application will be evaluated and scored individually by an objective review panel. All applications will be evaluated and scored first for Part A and subsequently, where applicable, for Part C

Evaluations and scoring for Part C will be conducted according to the following criteria:

- Methods and Activities: (35 points)
 - Can the methods and activities achieve the proposed objectives, consistent with the purposes of this announcement? Did the applicant propose appropriate methods and activities to collect and analyze emergency department TBI data consistent with the Program Requirements for Part C, including sampling methods and proposed staffing?
- Capacity to conduct TBIED surveillance: (20 points)
 - Did the applicant demonstrate authority to collect and maintain necessary TBI emergency department surveillance data

- consistent with the current CDC Central Nervous System Injury Surveillance Data Submission Standards, with demonstrated timeliness of case ascertainment, completeness of case ascertainment, and ability to analyze data? Did the applicant demonstrate appropriate existing capacity to collect and analyze abstracted data (e.g., describing TBI ED severity, circumstances, and early outcome) from a representative sample of cases reported to the TBI ED surveillance system?
- Management and Staffing: (20 points)
 - Does the staffing plan indicate the applicant's ability to carry out the objectives of the program? Considerations include: organizational structure, staff qualifications, experience, degree of stability maintaining current staff in critical positions, identified training needs or plan, and job descriptions and curricula vitae for both proposed and current staff. Does the applicant plan to coordinate activities with any other injury surveillance, prevention, and control programs or activities in the applicant's organizations?
- Goals and Objectives: (10 points)
 - Are the objectives specific, achievable, practical, measurable, time-linked, and consistent with the overall purposes described in this announcement?
- Evaluation: (10 points)
 - Did the applicant include plans to evaluate the attainment of proposed objectives, including plans to evaluate the sensitivity and predictive value positive of case ascertainment and the completeness and quality of data?
- Review of Literature and Statement of Need: (5 points)
 - Did the applicant review key literature relevant to the proposed project, and did the applicant describe needs within the jurisdiction to which the application is responsive?
- Budget and Justification: (not scored)
 Are the hydget reasonable clearly.
 - Are the budget reasonable, clearly justified, and consistent with stated objectives and proposed activities?
 - Has the applicant provided a budget to include funds for attending the annual grantees meeting?

Part D (TBISL)

Each application will be evaluated and scored individually by an objective review panel. All applications will be evaluated and scored first for Part A and subsequently, where applicable, for Part D.

Evaluations and scoring for Part D will be conducted according to the following criteria:

- Methods and Activities: (25 points)
- Can the methods and activities achieve the proposed objectives, consistent with the program requirements for Part D of this announcement?
- Capacity to link individuals with TBI to information about services: (20 points)
- If direct patient contact is proposed, did the applicant demonstrate authority to collect and maintain necessary TBI surveillance data? Did the applicant demonstrate legislative authority to contact individuals identified through TBI surveillance with information about services?
- Collaboration (20 points)
 - Has the applicant provided adequate information to assist the relationships between the program and other organizations, agencies, and health department units that will be involved in TBI linkage activities?
 - Has the applicant provided a clear and adequate description of appropriate partners and their stated roles?
- Management and Staffing: (10 points)
 Does the staffing plan indicate the applicant's ability to carry out the objectives of the program?
 Considerations include:
 Organizational structure, staff qualifications, experience, degree of stability maintaining current staff in critical positions, identified training needs or plan, and job descriptions
 - and curricula vitae for both proposed and current staff. Does the applicant plan to coordinate activities with any other injury surveillance, prevention, and control programs or activities in the applicant's organizations?
- Goals and Objectives: (10 points)
 - Are the objectives specific, achievable, practical, measurable, time-linked, and consistent with the overall purposes described in this announcement?
- Evaluation: (10 points)
 - Did the applicant include plans to evaluate the attainment of proposed objectives?
- Review of Literature and Statement of Need: (5 points)
 - Did the applicant review key literature relevant to the proposed project, and did the applicant describe needs within the

- jurisdiction to which the application is responsive?
- Budget and Justification: (not scored)
 - Are the budget reasonable, clearly justified, and consistent with stated objectives and proposed activities?
 - Has the applicant provided a budget to include funds for attending the annual grantees meeting?

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 for Injury Prevention and Control. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified by the National Center for Injury Prevention and Control in writing that their application did not meet submission requirements prior to the start date of the award.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above. Applications will be funded in order by score and rank determined by the review panel.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will be notified by telephone of selection for funding and to discuss proposed budget and 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.

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-7 Executive Order 12372
- 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

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. The progress report will serve as your noncompeting 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. Measures of Effectiveness.
 - f. Additional Requested Information.
- 2. Financial status report and annual progress report (see Appendix II for reporting requirements table), 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.

VI.4. Other Requirements

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. OMB clearance for the data collection initiated under this cooperative program is pending approval by OMB.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, 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: Angela Marr, Project Officer, 4770 Buford Hwy., NE., M.S. F–41, Atlanta, GA 30341–3724. Tel: (770) 488–1428. E-mail: amarr@cdc.gov.

CDC will host a program technical assistance conference call for this announcement on November 16, 2004, from 1 p.m. (e.s.t.) to 2 p.m. (e.s.t.). The

conference bridge number is (877) 368–9836 and the participant pass code is 852136. For financial, grants management, or budget assistance, contact: Angie Tuttle, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: (770) 488–2719. E-mail: AEN4@cdc.gov.

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: www.cdc.gov. Click on "Funding" then "Grants and Cooperative Agreements."

Dated: November 2, 2004.

William P. Nichols,

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

[FR Doc. 04–24809 Filed 11–5–04; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the charters of the committees listed in table 1 of this document for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed in table 1. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463 (5 U.S.C. app. 2)).

DATES: Authority for these committees will expire on the dates indicated in table 1 of this document unless the Commissioner formally determines that renewal is in the public interest.

TABLE 1.

Name of committee	Date of expiration
Anesthetic and Life Support Drugs Advisory Committee	May 1, 2006.
Blood Products Advisory Committee	May 13, 2006. May 30, 2006.
Drug Safety and Risk Management Advisory Committee	May 31, 2006.
Science Advisory Board to the National Center for Toxicological Research	June 2, 2006.
Peripheral and Central Nervous System Drugs Advisory Committee	June 4, 2006.
Psychopharmacologic Drugs Advisory Committee	June 4, 2006.
Transmissible Spongiform Encephalopathies Advisory Committee Science Board to the Food and Drug Administration	June 9, 2006. June 26, 2006.
Allergenic Products Advisory Committee	July 9, 2006.
Cardiovascular and Renal Drugs Advisory Committee	August 27, 2006.
Endocrinologic and Metabolic Drugs Advisory Committee	August 27, 2006.
Oncologic Drugs Advisory Committee	September 1, 2006. October 7, 2006.
Dermatologic and Ophthalmic Drugs Advisory Committee	October 7, 2006.
Cellular, Tissue, and Gene Therapies Advisory Committee (formerly Biological Response Modifiers Advisory Committee)	October 28, 2006.

FOR FURTHER INFORMATION CONTACT:

Linda A. Sherman, Advisory Committee Oversight and Management Staff (HF– 4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

Dated: October 29, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–24842 Filed 11–5–04; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel Clinical Research.

Date: November 17–18, 2004. Time: November 17, 2004, 8 a.m. to Adjournment.

Ágenda: To review and evaluate grant applications.

Place: Omni Charlottesville Hotel, 235 West Main Street, Charlottesville, VA 22902.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Institutes of Health, NCRR, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1076, MSC 4874, Bethesda, MD 20892, (301) 435–0814, lambert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS.)

Dated: October 28, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-24795 Filed 11-5-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as