Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total			4200

Dated: December 22, 2004.

B. Kathy Skipper,

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

[FR Doc. 04–28617 Filed 12–29–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–050557]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 or send comments to Dale Verell, CDC Alternate OMB Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Public Health Performance Standards Program State Public Health System Assessment (OMB 0920–0557)—Extension—Office of the Director, Centers for Disease Control and Prevention (CDC).

The Office of the Director, CDC is proposing to extend the currently approved National Public Health Performance Standards Program State Public Health System Assessment. From 1998 ''2002, the CDC National Public Health Performance Standards Program convened workgroups with the National Association of County and City Health Officials (NACCHO), The Association of State and Territorial Health Officials (ASTHO), the National Association of Local Boards of Health (NALBOH), the American Public Health Association (APHA), and the Public Health Foundation (PHF) to develop performance standards for public health systems based on the essential services of public health.

CDC is now proposing to extend the formal, voluntary data collection that assesses the capacity of state public health systems to deliver the essential services of public health. Electronic data submission will be used when state health departments complete the public health assessment.

The extension will provide additional time for state public health agencies to undertake the assessment. Some states have sought to include mention of the assessment in legislation or regulations and are planning to respond to the assessment in the upcoming year. The focus on bioterrorism and other emerging issues diverted resources and attention from immediate use of the assessment since its national release in 2002. A two-year extension will provide additional needed time.

The estimated annualized burden for each extension year is 105 hours.

No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
7	1	15	105
Total			105

Dated: December 22, 2004.

B. Kathy Skipper,

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

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Youth Violence Prevention through Community-Level Change

Announcement Type: New.

Funding Opportunity Number: CE05–020.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates:

Letter of Intent Deadline: January 31, 2005.

Application Deadline: March 30, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under both section 391 (a) and 301 (a) of the Public Health Service Act, 42 U.S.C. section 280b (a).

Background: Youth violence has been linked to a variety of factors, including individual, family, community, and societal characteristics. While much research has been conducted on

interventions with individuals and families, fewer interventions have focused on variables at the broader community level.

Purpose: The purpose of the program is to announce the availability of fiscal year (FY) 2005 funds for a cooperative agreement to assess the efficacy or effectiveness of interventions designed to change community characteristics and social processes to reduce rates of youth violence perpetration and victimization. This program addresses the ''Healthy People 2010'' focus area(s) of Injury and Violence Prevention.

Measurable outcomes of the program will be in alignment with the following performance goal(s) for the National Center for Injury Prevention and Control (NCIPC): Conduct a targeted program of research to reduce injury-related death and disability.

Special Guidelines for Technical Assistance: Conference Call: Technical assistance will be available for potential applicants on one conference call. The call for eligible applicants will be held on (January 20, 2005) from 2:30 p.m. to 4 p.m. (Eastern Time). The conference can be accessed by calling 888–528–9061 and entering access code 21415.

The purpose of the conference call is to help potential applicants:

1. Understand the Request for Application Process for the RFA # CE05–020 Youth Violence through Community-Level Change.

2. Understand the scope and intent of the RFA # CE05–020 Youth Violence Prevention through Community-Level Change.

3. Become familiar with the Public Health Services funding policies and application and review procedures. Participation in this conference call is not mandatory. At the time of the call, if you have problems accessing the conference call, please call 404–639–7550 for assistance.

Research Objectives: There are a number of characteristics of communities that increase the probability of youth violence. Crime and violence tend to be high in areas in which at least 20 percent of the residents are poor (Lamison-White, 1996). These areas are often characterized by high concentrations of poverty and unemployment, high levels of residential instability, family disruption, crowded housing, drug-distribution networks, and low community participation (Sampson & Lauritsen, 1994). These areas also tend to have high rates of school dropouts, high rates of substance abuse and teenage pregnancy, and a disproportionate number of households headed by women (Eller, 1996; Proctor & Dalaker, 2002; Reiss & Roth, 1993).

In addition to their demographic characteristics, economically poor neighborhoods differ from more affluent neighborhoods in a number of ways. Poor neighborhoods tend to be characterized by disorganization or a lack of neighborhood cohesion, and as a result, frequently lack effective social controls (Elliot *et al.*, 1996; Sampson, Raudenbush & Earls, 1997). Factors such as high levels of transiency make it difficult for individuals to establish common values and norms, and to develop informal support networks. As a result, people living in such neighborhoods often experience a sense of social isolation and exhibit lower levels of attachment to the community. High levels of social disorganization also limit the ability of community residents to supervise and control adolescent peer groups, especially gangs (Sampson & Lauritsen, 1994).

Research funded under this announcement is expected to further our understanding of how community-level interventions can reduce violence. A clear distinction is made here between community-based interventions, which are programs that are implemented in the community and/or by a community-based organization, from community-level interventions, which target community-level factors such as those described above (*e.g.*, poverty, social cohesion, residential instability, neighborhood disorganization, etc.). Recipients are expected to implement and conduct an evaluation of an intervention that targets modifiable community-level variables that have been shown to increase the risk of youth violence and/or enhance the protective factors that decrease the risk of youth violence.

Priority will be given to the evaluation of primary prevention interventions and programs that focus on the social and economic environment (relationships among people and settings) and/or the physical environment, over those that focus on criminal justice responses (*e.g.*, community policing, arrest strategies). These include:

- Strategies to increase social integration and cohesion by increasing community participation as well as formal and informal social support.
- Strategies to improve the physical and social characteristics of neighborhoods (*e.g.*, through environmental design changes).
- Strategies to improve financial, housing, and/or employment issues in impoverished areas.
- Efforts to deconcentrate areas with high rates of poverty and violence.
- Strategies to increase formal and/or informal supervision of youth (*e.g.*, access to after school programs).
- Strategies to reduce community density and availability of alcohol and drugs.
- Strategies to improve family stability by changing community characteristics (*e.g.*, increasing the presence of or access to family support services; increasing neighborhood or civic support to facilitate family cohesion).
- Strategies focusing on increasing communities' investment in schools and commitment to education (*e.g.*, school-community partnerships; policies or incentives to increase school attendance and graduation rates).

The proposed research is expected to detail one or more specific interventions for community-level variables, rather than propose a process for determining which interventions are appropriate for the chosen community. This program is intended to assess the effects of a community-level intervention alone, not as part of a larger multi-level intervention trial (a multi-level intervention trial is defined here as one that addresses the effects of community-level factors separately, and in combination with one or more components that address individual-level or family-level factors).

Research funded under this announcement is expected to adhere to high scientific standards, and to incorporate the following elements:

- Interventions and measures appropriate to the developmental level(s) and cultural/ethnic backgrounds of the population of interest.
- Interventions that are theoretically justified (*i.e.*, include a conceptual model or theory of change, with proposed mediators and moderators, for how the intervention will produce the intended reductions in youth violence), and supported with epidemiologic, methodologic, and behavioral research.
- Stringent and rigorous evaluation designs, namely experimental and quasi-experimental designs with appropriate baseline/pre-intervention data, post-intervention data, and at least one follow-up data collection point; data from at least one comparison or control community; and data collected from multiple sources.
- Robust evaluation designs that collect and analyze process data (*e.g.*, intervention fidelity and program exposure) and outcome data associated with the intervention using measures with documented validity and/or reliability. Outcomes and impacts

appropriate for this program include those that are measured at the neighborhood or community level and that focus on risk and protective factors specific to that level of intervention. Examples include: police records of neighborhood or community arrests for violent crimes, violent school incidents (aggregated to the school or system level), violent injury-related hospital or emergency department data aggregated by neighborhood or community, or intake rates for juvenile detention facilities.

• Evaluation designs that make use of multiple sources of data (where possible) to improve validity and reliability on each outcome selected.

• Evaluation designs that collect information on intervention processes, outcomes, mediators that lead to change in those outcomes and data that document the economic costs of the intervention from the societal and programmatic perspectives (*e.g.*, cost to train implementers, implementation costs, and costs borne by participants). Measures are expected to have documented validity and reliability whenever possible. Outcomes are expected to be assessed at the appropriate level of intervention.

• Data analytic plans that are appropriate to the intervention, research design and hypotheses, data collection measures, and project period, and that anticipate and evaluate the effects of threats to the internal and external validity of the specified research design.

Rigorous evaluations are needed to determine the effectiveness of interventions, programs, and policies addressing the prevention of violence. Experimental designs are strongly encouraged. However, NCIPC will consider other evaluation designs, if justified, as required by the needs and constraints in a particular setting.

For effective interventions, it is possible to do cost-effectiveness studies. To be comparable to other cost effectiveness studies, they should follow the guidelines in the following references:

Gold MR, Siegel JE, Russell LB, Weinstein MC. Cost-effectiveness in Health and Medicine. New York: Oxford University Press, 1996.

Haddix AC, Teutsch SM, Corso, PS. Prevention Effectiveness: A Guide to Decision Analysis and Economic Evaluation. Second Edition. New York: Oxford University Press, 2003.

Activities: Awardee activities for this program are as follows:

• Establish goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.

• Develop a research protocol for Institutional Review Board (IRB) for review and approval by all cooperating institutions participating in the research project.

• Design and develop intervention components, data collection instruments, implementation and evaluation protocols, and data management procedures.

• Pilot test research instruments for data collection.

• Collect and compile process and outcome data. Develop a protocol/manual documenting the intervention and the manner in which it was implemented, including any information on activities occurring prior to the start of the intervention, such as stakeholder meetings, collaborative building, or focus groups.

• Collect data on the economic costs of program implementation for use in economic evaluations.

• Prepare data for analysis and publication.

• Analyze data and disseminate findings through peer-reviewed journals and presentations.

• Conduct one reverse site visit to meet with CDC staff in Atlanta on an annual basis.

• Complete all required reports as specified under Section VI.3 Reporting.

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 scientific and programmatic consultation. CDC will collaborate with project staff on decision-analyses, programmatic issues, and dissemination of the study results in publications and presentations.

• Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is finished.

• CDC staff will monitor and review scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.

II. Award Information

Type of Award: Cooperative Agreement.

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

Mechanism of Support: U49.

Fiscal Year Funds: 2005.

Approximate Total Funding: $1,200,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: Two.

Approximate Average Award: $600,000 (This amount is for the first twelve month budget period and includes both direct and indirect costs. Approximately $4,800,000 total is available over the entire four years of the project period.)

Floor of Award Range: None.

Ceiling of Award Range: $600,000 (This ceiling is for the first twelve month budget period and includes both indirect and direct costs.)

Anticipated Award Date: September 1, 2005.

Budget Period Length: Twelve months.

Project Period Length: Four 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 public and private nonprofit and for profit organizations and by governments and their agencies, such as:

• Public nonprofit organizations.
• Private nonprofit organizations.
• For profit organizations.
• Small, minority, women-owned businesses.
• Universities.
• Colleges.
• Research institutions.
• Hospitals.
• 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 the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
• Political subdivisions of States (in consultation with States).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local

government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, which includes both direct and indirect costs, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

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

- Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing violence prevention research in peer-reviewed journals.
- Effective and well-defined working relationships within the performing organization and with outside entities expected to participate in the proposed research that will ensure implementation of the proposed activities, as evidenced by letters of support from the performing organization and outside entities.
- The overall match between the applicant's proposed research and the program priorities as described under the heading, ''Research Objectives''.
- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- Principal Investigators (PIs) are encouraged to submit only one proposal in response to this program announcement. With few exceptions (*e.g.*, research issues needing immediate public health attention) only one application per PI will be funded under this announcement.
- *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.

Individuals Eligible to Become Principal Investigators: Principal Investigator qualifications are as follows:

- A principal investigator who has documented prior training and experience in conducting efficacy and effectiveness trials as evidenced by peer-reviewed publications of such studies, or current or previous research grants for efficacy or effectiveness trials.
- A principal investigator who has conducted violence prevention research, published the findings in peer-review journals, and has the specific authority and responsibility to carry out the proposed research.

Any individual with the skills, knowledge, and resources necessary to carry out the proposed injury research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html.*

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 Application Submission

Letter of Intent (LOI): 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, 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:* Twelve point unreduced.
- *Paper size:* Eight and a half by eleven inches.
- *Page margin size:* One inch.
- Single-spaced.
- Printed only on one side of page.
- Written in English, avoid jargon.

Your LOI must contain the following information:

- Descriptive title of the proposed research.
- Name, address, E-mail address, and telephone number of the Principal Investigator.
- Names of other key personnel.
- Participating institutions.
- Number and title of this Program Announcement (PA).
- A brief description of the proposed intervention and evaluation plan.

Application: Follow the PHS 398 application instructions for content and formatting of your application. If the instructions in this announcement differ in any way from the PHS 398 instructions, follow the instructions in this announcement. For further assistance with the PHS 398 application form, contact PGO-TIM staff at 770–488–2700, or contact GrantsInfo, Telephone (301) 435–0714, E-mail: *GrantsInfo@nih.gov.*

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. Your DUNS number must be entered on line 11 of the facing page of the PHS 398 application form. 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/pubcommt.htm.*

This announcement uses the non-modular budgeting format. Provide a detailed budget for each activity undertaken, with accompanying justification of all operating expenses that is consistent with the stated objectives and planned activities of the project.

In addition to the instructions provided in the PHS 398 for writing the Description on page 2 of the PHS 398 form, structure the Description using the following components: (1) Statement of the problem, (2) purpose of the proposed research, (3) methods, including study population, data sources and any statistical analyses to be performed, and (4) implications for prevention.

The Description (abstract) should answer the following questions:

- Does the Description state the hypothesis?
- Does the Description describe the objectives and specific aims?

• Does the Description state the importance of the research and how it is innovative?

• Does the Description outline the methods that will use to accomplish the goals?

Is the language of the Description simple and easy to understand for a broad audience?

You must include a research plan with your application. Your research plan should address activities to be conducted over the entire project period. Please follow the content requirements below in developing your research plan instead of those listed for the Research Plan in the PHS 398.

The research plan should consist of the following information:

1. *Purpose of the Proposed Research:* Describe the goals and objectives the proposal is designed to achieve in the short and long term. Specific research questions, hypotheses, and implications for prevention should also be included.

2. *Program Participants:* Describe the demographic and geographic characteristics of the community and/or neighborhood targeted by the intervention. This section should include incidence, prevalence, morbidity, and/or mortality rates associated with youth violence within that community. In addition, the proposal should provide evidence that the recipient (or collaborating partner) has access to the target community, and that the participation by the target community in the intervention will be adequate to produce the intended outcomes.

3. *Intervention:* Describe the proposed strategies or components of the intervention and the plan for implementing the intervention. Proposals should explicate the theoretical and empirical justification for the potential effectiveness of the intervention for reducing youth violence in the target community. This should include discussion of the modifiable risk and protective factors that will be influenced by the intervention of interest. The proposal should describe the location or setting in which the intervention component(s) will occur, and describe the relevance of this setting to the strategy and desired outcomes. The proposal should also describe how intervention fidelity will be monitored and measured.

4. *Methods:* Describe the proposed evaluation design, data sources, methods and analysis plan for assessing the efficacy or effectiveness and/or for conducting an economic evaluation. The specific type of evaluation method chosen should reflect the nature of the intervention, feasibility, and ethical considerations. Potential threats to the validity of the study should be described along with how such threats will be recognized and addressed. The status of all necessary measurement instruments should be described. If any materials are not extant, the methods and time frame for measure development, pilot testing, and validation should be given. For data collected from archival records (*e.g.*, hospital records, police records, etc.) the proposal should discuss issues of accessibility, reliability, and validity of those data.

5. *Project Management:* Provide evidence of the expertise, capacity, and community support necessary to successfully implement and evaluate the intervention to reduce community indicators of youth violence. Existing and proposed positions for the project should be described by job title, function, general duties, level of effort and allocation of time. Management operation principles, structure, and organization should also be noted.

6. *Collaborative Efforts:* List and describe any current or proposed collaboration with government, health, community-or faith-based organizations, minority organizations, and/or other researchers and academic institutions. Include letters of support and memoranda of understanding that specify the nature of past, present, and proposed collaborations, and the products/services/activities that will be provided by and to the applicant.

The research plan should be no more than 25 pages (eight and a half by eleven inches in size), single-spaced, printed on one side only, with one-inch margins on all sides, and unreduced 12-point font.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.'' For additional help in preparing your application, please see the ''frequently asked questions'' section on the NCIPC Web page at: *http://www.cdc.gov/ncipc/res-opps/2004pas.htm*.

IV.3. Submission Dates and Times

LOI Deadline Date: January 31, 2005. 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: March 30, 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 carrier's 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 application is not received in the CDC Procurement and Grants office by 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

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 relating to the conduct of research will not be released until the appropriate assurances and IRB approvals are in place.

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:

Address for Express Mail or Delivery Service: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control, 2945 Flowers Road, Yale Building, Room 2054, Atlanta, Georgia 30341.

Address for U.S. Postal Service Mail: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K–62, Atlanta, GA 30341, Telephone: 770–488–4037, Fax: 770–488–1662, E-mail: *cipert@cdc.gov.*

Application Submission Address: Submit the original and one hard copy of your application by mail or express delivery service to: Technical Information Management—CE05–020, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

At the time of submission, four additional copies of the application, and four copies of all appendices must be sent to:

Address for Express Mail or Delivery Service: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control, 2945 Flowers Road, Yale Building, Room 2054, Atlanta, Georgia 30341.

Address for U.S. Postal Service Mail: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K–62, 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.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria equally in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The review criteria are as follows:

Significance: Does this study address an important problem? 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?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the selection of a research design justified, and is the research design appropriate to answer the research question?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

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? If collaborations are being proposed, are the partners and their skills and expertise well described? Can proposed collaborations reasonably be expected to improve the quality of the implementation and evaluation of the intervention?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

Intervention: Is the potential effectiveness of the proposed intervention within the target community theoretically justified and supported with epidemiologic, methodological, and behavioral research? How feasible is the implementation of the intervention as proposed? Can the intervention reasonably be predicted to produce the expected reductions in youth violence? Is the setting of implementation appropriate?

Protection of Human Subjects From Research Risks: Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects? This will not be 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.

Inclusion of Women and Minorities in Research: 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; and (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.

Inclusion of children as participants in research involving human subjects: The NIH maintains a policy that children (*i.e.*, individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. NCIPC has adopted this policy for this announcement.

All investigators proposing research involving human subjects should read the ''NIH Policy and Guidelines'' on the inclusion of children as participants in research involving human subjects that is available at: *http://grants.nih.gov/grants/funding/children/children.htm.*

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The budget is not scored during the primary review.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by the NCIPC. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance

through the review process. Applicants will be notified that their application did not meet submission requirements. Applicants will be notified 45 days prior to the award date regarding their application status.

Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by the NCIPC in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

- Undergo a process in which only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Applications deemed to have the highest scientific merit will receive a second programmatic level review by the Science and Program Review Subcommittee (SPRS) of the Advisory Committee for Injury Prevention and Control (ACIPC).

Applications that are complete and responsive may be subjected to a preliminary evaluation (streamline review) by an external peer review committee, the NCIPC Initial Review Group (IRG), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRG. 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. Those applications judged to be competitive will be further evaluated by a dual review process.

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee IRG, 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.

The primary review will be an external peer review conducted by the IRG. All applications will be reviewed for scientific merit using current NIH criteria (a scoring system of 100–500 points) to evaluate the methods and scientific quality of the application.

The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of the ACIPC. The external 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 will be the same as those considered by the SPRS.

The secondary review committee'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 committee 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 ''CDC Injury Research Agenda.''

d. Budgetary considerations.

Award Criteria: Criteria that will be used to make award decisions during the programmatic review include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.
- Geographic diversity.
- Racial/ethnic diversity.
- Balance of intervention approaches and strategies.
- Consistency with research priorities in CDC's Injury Research Agenda.
- Availability of funds within categories of violence and injury funding streams.

V.3. Anticipated Announcement and Award Dates

September 1, 2005.

VI. Award Administration Information

VI.1. Award Notices

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

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

VI.2. Administrative and National Policy Requirements

45 CFR part 74 and part 92

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

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–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–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.
- AR–23 States and Faith-Based Organizations.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- AR–25 Release and Sharing of Data.

Starting with the December 1, 2004 receipt date, all ''Requests for

Applications (RFA)/Program Announcements (PA)'' soliciting proposals for individual research projects of $500,000 or more in total (direct and indirect) costs per year require the applicant to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing and release, including information on the timeliness of the data and the name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing and release may also be appropriate in other sections of the application (*e.g.* background and significance, or human subjects requirements). The content of the data sharing and release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing and release plan will not count towards the application page limit and will not factor into the determining scientific merit or the priority scoring. Investigators should seek guidance from their institutions on issues related to institutional policies, and local IRB rules, as well as local, state and federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or by visiting the NCIPC Internet Web site at: *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 Web site) 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. 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: Charlene Baker, PhD, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K–60, Atlanta, GA 30341, Telephone: 770–488–1737, E-mail: *asu6@cdc.gov.*

For questions about peer review, contact: Gwendolyn Cattledge, PhD, Scientific Review Administrator, 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: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: December 23, 2004.

William P. Nichols,

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

[FR Doc. 04–28619 Filed 12–29–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., February 16, 2005; 8:30 a.m.–12 p.m., February 17, 2005.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333. Telephone (404) 639–8008.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating TB.

Matters to be Discussed: Agenda items include issues pertaining to Global TB epidemiology and public health response, nucleic acid amplification testing (NAAT), and other TB related topics.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Paulette Ford-Knights, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., M/S E–07, Atlanta, Georgia 30333, telephone (404) 639–8008.

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 the Agency for Toxic Substances and Disease Registry.

Dated: December 20, 2004.

B. Kathy Skipper,

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

[FR Doc. 04–28615 Filed 12–29–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2490–N]

CLIA Program; Continued Approval of the American Association of Blood Banks for Deeming Authority

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

ACTION: Notice.

SUMMARY: This notice announces the re-approval of the American Association of Blood Banks (AABB) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. The initial exemption