Dated: November 12, 2004.

Alma L. Golden,

Deputy Assistant Secretary for Population Affairs.

[FR Doc. 04–25758 Filed 11–19–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

2005 White House Conference on Aging Policy Committee

AGENCY: Administration on Aging, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2), notice is hereby given of the third Policy Committee meeting concerning planning for the 2005 White House Conference on Aging. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

DATES: The meeting will be held Wednesday, December 1, 2004, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the American Association of Homes and Services for the Aging, 2519 Connecticut Avenue, NW., Conference Room, Washington, DC 20008–1520.

FOR FURTHER INFORMATION CONTACT: Nora Andrews, (301) 443–2874, or e-mail at *Nora.Andrews@whcoa.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to the Older Americans Act Amendments of 2000 (Pub. L. 106–501, November 2000), the Policy Committee will meet to discuss delegate participation, the conference theme, and to review and discuss work of the subcommittees.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 04–25747 Filed 11–19–04; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Cooperative Agreement Program for the National Academic Centers of Excellence on Youth Violence Prevention

Announcement Type: New.

Funding Opportunity Number: CE05–018.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates:

Letter of Intent Deadline: December 22, 2004.

Application Deadline: February 10, 2005.

I. Funding Opportunity Description

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

Purpose: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2005 cooperative agreement funds to establish up to ten National Academic Centers of Excellence (ACE) on Youth Violence Prevention, serving as national models for the prevention of youth violence. The purpose of the Centers is to help communities prevent youth interpersonal violence. As of 2005, Centers will be supported for up to ten years to promote a stable, long term focus on the complex problem of youth violence, fostering multidisciplinary and multi-sectoral interactions that can stimulate scientific creativity, speed new developments in youth interpersonal violence research and practice, and hasten translation of knowledge into health and community practice. Centers are expected to actively foster an environment conducive to reciprocally beneficial collaborations among health scientists, social scientists and the affected communities with the common goal of reducing youth interpersonal violence.

Youth violence is defined as: The intentional use of physical force or power, threatened or actual, exerted by or against children, adolescents or young adults, ages 10–24, which results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment, or deprivation. It includes violence between individuals or groups who may or may not know each other. It frequently takes place outside the home, in the streets, or in institutional settings, such as schools, workplaces, and prisons. Hereafter, youth violence and youth interpersonal violence will be used synonymously.

This program addresses the ''Healthy People 2010'' focus area of Injury and Violence Prevention. For a copy of ''Healthy People 2010'' visit the Internet site: *http://www.health.gov/healthypeople*.

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

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.
3. 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 during one conference call.

The call for eligible applicants will be held on December 9, 2005 from 2:30 p.m. to 4 p.m. (eastern time). The conference can be accessed by calling 1–888–528–9061 and entering access code 18046.

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

1. Understand the Request for Application Process for the RFA (CE05–018) for the National Academic Centers of Excellence on Youth Violence Prevention.
2. Understand the scope and intent of the RFA (CE05–018) for the National Academic Centers of Excellence on Youth Violence Prevention.
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.

Program Objectives: The goal of this program is to reduce the incidence of youth violence in the defined community by achieving the following objectives:

- Monitoring the magnitude and distribution of youth interpersonal violence.
- Building the scientific infrastructure necessary to support the development and widespread application of effective youth violence prevention interventions.
- Promoting interdisciplinary research strategies to address the problem of youth violence.
- Fostering collaboration between academic researchers and communities.

• Mobilizing and empowering communities to address the problem of youth violence.

Activities: Awardee activities during the course of the five-year award for this program are listed below. Additional information on the program activities is provided in the application content of this announcement.

• Apply and refine a logic model for the academic center of excellence adapted from the national ACE Program conceptual framework or logic model (See Appendix 1 for a description) to fit the specific inputs, activities, outputs, and outcomes of the proposed center.

• Develop and implement a center evaluation plan and demonstrate how the center's evaluation contributes to CDC's national program evaluation, including the core performance indicators (see Appendix 2 for a list of the indicators.)

• Develop, implement and evaluate center projects in conjunction with the center's ''defined community'', (whether geographic or a non-geographic sub-grouping) which the center's activities will serve. Community is defined as a group of people who share some or all of the following: geographic boundaries; a sense of membership; culture and language; common norms, interests, or values; and common health risks or conditions (CDC/ATSDR Principles of Community Engagement, IOM 2002). Community refers to a population that has a distinct identity. It can mean residents of a geographic area, be that a catchment's area, neighborhood, school district, city, county or region within a county. It can be used with a modifier or clause to describe a non-geographically based sub-grouping such as, but not exclusively: a community of youth violence prevention workers, a community of health professionals, or an ethnic or language community.

• Establish or maintain a center community advisory committee to work with the defined community to achieve center goals. See Appendix 3, the glossary, for a definition and composition of the community committee.

• Establish and maintain partnerships (*e.g.*, state and local health departments, youth violence prevention and youth serving organizations, community groups and agencies, faith-based organizations and local businesses, and academic units), and include these partners, when applicable, in the center activities. See Appendix 3, the glossary, for a definition and composition of partnerships.

• Establish and/or enhance surveillance systems to better measure the problem of youth violence and the impact of center activities and research in the defined community.

• Identify youth violence prevention priorities within the defined community.

• Carry out the center's participatory, community-based core youth interpersonal violence research project(s) and the center's five-year research agenda. Each center is required to conduct at least one core research project consistent with both the NCIPC Research Agenda and NCIPC's mission.

• Plan the core research project in collaboration with community partners.

• Refine, carry out and evaluate the center's community mobilization plan in partnership with a community's individuals, groups, and organizations on a participatory and sustained basis. (See Appendix 3, the glossary, for a definition of community mobilization.)

• When appropriate, collaborate with CDC, community partners, and other ACE centers to develop and finalize design for studies and activities, methodology, data collection measures, methods, and analyses and disseminate the results through presentations and publications to broad audiences, including public health.

• Collect and report necessary data and information to CDC to assess progress toward centers' goals and objectives and monitor overall performance. This should include, but will not be limited to, information related to the ACE Performance Indicators. (See Appendix 2 for list of indicators).

• Develop an infrastructure of personnel and resources to support center functions and processes. This infrastructure should ensure that adequate personnel, facilities, technology, and university support exists to accomplish the goals and objectives of the center.

• Provide training, technical assistance, and mentoring to health professionals, researchers, students, community members, and other partners, as appropriate, including other funded Academic Centers of Excellence on Youth Violence Prevention.

• Obtain approval of the study protocol by the recipient's local Institutional Review Board (IRB). Collaborate with CDC in the development of a research protocol for CDC Institutional Review Board (IRB) review, if appropriate.

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 input, serve as a scientific and professional resource, and collaborate with ACE staff on research, interpretation of findings, and the production of publications and presentations to disseminate study results.

• Facilitate regular communication between CDC and the grantees to include, but not limited to conference calls and meetings, including the convening of annual ACE meetings to facilitate research collaboration and information sharing among centers.

• Review, monitor, and evaluate scientific and operational accomplishments to assure progress toward program goals and objectives. The review will be based on the center's logic model and the critical components of the model that are related to the achievement of core performance indicators. The review process will include but not be limited to conference calls, site visits, annual meetings, and required reports.

• Collect, organize and disseminate information on ACE activities, including research. Inform recipients about any CDC policies, laws, and regulations pertaining to public health research and programmatic activities, conduct inquiries concerning allegations of scientific misconduct, and take necessary steps to bring program into compliance.

• When appropriate, assist in the development of a research protocol(s) for IRB review by all performance sites involved in the research project. If CDC researchers are significantly involved in the project, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

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: $6,800,000 (This amount is an estimate, and is subject to availability of funds).

Approximate Number of Awards: 7–10.

Approximate Average Award: $830,000.

Floor of Award Range: $680,000.

Ceiling of Award Range: $980,000 (Ceilings are for the first 12-month budget period and include both indirect and direct costs).

Anticipated Award Date: September 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 site visits), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Eligible applicants are academic institutions/centers with a focus on health, such as:

- Public and private nonprofit universities;
- Colleges;
- University-associated teaching hospitals.

Eligible applicants may enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application. A *Bona Fide* Agent is an agency/organization identified by the academic institutions/centers as eligible to submit an application under the academic institutions/centers eligibility in lieu of an academic institutions/centers application. If you are applying as a *bona fide* agent of academic institutions/centers, you must provide a letter from the academic institutions/centers 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 announcement.

III.3. Other

CDC will not accept and review applications with budgets greater than the ceiling of the award range. Applications with budgets that exceed the ceiling of the award, which includes both direct and indirect costs, 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.

- Late applications will be considered non-responsive. See section ''IV.3 Submission Dates and Times'' for more information on deadlines.

A National Academic Center of Excellence on Youth Violence Prevention is expected to have the following core components which together address the objectives of a center: (1) Administrative and Infrastructure Core, (2) Surveillance and Research Core and (3) Outreach and Education Core. The essential characteristics of a National Academic Center of Excellence on Youth Violence Prevention are as follows:

- A core faculty in fields such as public health, epidemiology, biostatistics, social sciences, behavioral and environmental sciences, health and youth policy, economics, evaluation, and health administration.
- Established working relationships with multidisciplinary faculty in the fields listed above and in other disciplines, such as, but not limited to, medicine, psychology, nursing, social work, education, urban planning, youth development and business.
- Graduate training programs relevant to youth violence prevention.
- Demonstrated relationships with a broad range of community partners and expertise in developing, implementing and evaluating community-based youth participatory research and mobilization activities.
- Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing community-based participatory research (CPBR) in peer-reviewed journals. (See Appendix 3, the glossary, for a definition of Community-based participatory research).
- Effective and well-defined working relationships within the performing organization and with outside entities (as evidenced by letters of support and in memoranda of understanding).
- An overall match between the applicant's proposed research objectives and the program objectives as described under the heading, ''Program Objectives''.

Only one application per institution will be accepted.

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 conducted community-based youth violence prevention research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

Applications that do not meet the above requirements will be considered non-responsive.

Individuals with the above-listed skills, knowledge, and resources necessary to carry out the proposed research are 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. Each institution may submit only one application per round of competition.

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, attachments 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): Prospective applicants are asked to submit a Letter of Intent (LOI) that includes the following information and written in the following format:

- *Maximum Number of Pages:* Three.
- *Font Size:* 12-point unreduced.
- *Paper Size:* 8.5 by 11 inches.
- *Page Margin Size:* One inch.
- Printed only on one side of page.
- Single spaced.
- Written in plain language, avoid jargon.

Your LOI must contain the following information:

- Descriptive title of the proposed Center.
- Name, address, e-mail address, telephone number, and facsimile number of the Principal Investigator.
- Names of other key personnel.
- Participating institutions.
- Number and title of this RFA.

- Brief description of the proposed center's research focus (a three to four line description).
- Brief description of the scope and intent of the proposed center work (maximum one paragraph).

Note: Attachments, booklets, or other documents will not be accepted with the LOI.

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*.

Your application should address activities to be conducted over the entire five-year project period.

For more information, see the CDC Web site at: *http://www.cdc.gov/funding.htm*.

This announcement uses just-in-time concepts. This announcement uses the non-modular budgeting format. The application narrative should consist of the following information:

(1) *Administrative and Infrastructure Core:* To ensure that applicants have the administrative and infrastructure capacity to achieve the program objectives, applicants should describe the following:

(a) Defined Community: Applicants need to define and describe the center's mission and the primary community (whether geographic or a non-geographic sub-grouping) that the center's activities will serve. (See Appendix 3, Glossary of Terms, for a definition of community). Applicants should, at a minimum, address the following characteristics of the defined community, as they pertain to the type of community chosen: the size of the community; the demographic make up, socioeconomic and cultural characteristics; levels of youth violence and the prevalent risk and protective factors of, or encountered by, the defined community; the youth violence prevention infrastructure, levels of organization and support for interpersonal youth violence prevention interventions in the defined community; and the existence of health, education, justice, and other policies related to youth violence prevention in the defined community. Applicants should describe the linkages between the center and the defined community and document appropriate levels of engagement and collaboration that reflects the ability to carry out proposed center activities.

(b) Evaluation: Applicants need to describe how they will develop a plan for evaluating the progress of the center in achieving its goals and the national performance indicators. Applicants should describe their capacity to: establish a five-year evaluation plan; conduct center-level evaluation; and collect data to determine the performance of the center using the national performance indicators. (See Appendix 2 for a description of Developing an Evaluation Framework: National Academic Centers of Excellence in Youth Violence Prevention.) To assure that applicants have this capacity, applicants should, at a minimum:

(i) Describe their center-level logic model specifying the center's youth violence prevention priorities and expected outcomes. Within the logic model, applicants should define the inputs, activities, outputs, outcomes, evaluation, and contextual conditions for the center. The logic model should be adapted from the national ACE Program conceptual framework (See Appendix 2.) In addition to the logic model, a narrative description of each component must be included. Please include the center's mission within the narrative, limiting the mission statement to one to two sentences. Further, within this narrative briefly describe how the center's model is related to the national ACE Program conceptual framework.

(ii) Document experiences of center faculty in conducting process, outcomes, and impact evaluations in the past five years and address how the center will continue or enhance its evaluation expertise as it relates to the center-level evaluation.

(iii) Describe how they will create a five-year plan for evaluating the critical components of the center's logic model. The plan should be developed in collaboration with the center's community committee and center partners and include: a description of how the plan will be developed; identification of resources and staff responsible for evaluation; specific evaluation questions, goals and objectives; quantitative and qualitative assessment of the centers activities to demonstrate program accomplishments and challenges; and a plan for identifying emerging challenges.

(c) Infrastructure: Applicants should describe an infrastructure of personnel and resources required to develop center functions and processes. Applicants should have the capacity to recruit, hire, and retain faculty and staff with the expertise to implement center projects and activities; acquire, manage, and maintain the communications and information systems necessary to operate an ACE; and acquire and maintain university support for the center. To assure that applicants have this capacity, applicants should, at a minimum:

(i) Provide an organizational chart for the center showing all organizational units and functions. The chart should also reflect the activities articulated in the center's logic model.

(ii) Describe the center's staffing and management plan. Describe each proposed position and discuss how the position provides the scientific and technical expertise needed to carry out both research and non-research activities. Describe the minimum criteria and the required expertise for each position. Describe the qualifications of the proposed staff, how the proposed staff will interact with each other, with other faculty outside the center, and with the university's leaders to accomplish the center's goals and objectives. This discussion should highlight the following center staff: leadership; research; evaluation; communication and dissemination; training; information management; and fiscal and administration staff.

(iii) Describe how your center will be integrated within the university structure. Describe the facilities in which staff will work and how these facilities enhance the center's ability to complete the proposed activities. Describe the center's plan to enhance its core capacity over the five-year period, including the commitment and capability to obtain the communication, information systems, and other tools necessary to accomplish goals and objectives (i.e., computer equipment, telephones, facsimile machines, scanners, scientific software, etc.).

(iv) Describe plans for cross-disciplinary training of new and established investigators, including: adequacy of facilities for workshops, seminars and other educational activities; capacity to train predoctoral and/or postdoctoral students in multi-disciplinary interpersonal youth violence prevention research; and experience in effectively conducting mentoring and career development activities.

(d) Collaborations/Partnerships: Applicants need to develop and describe the nature and range of partnerships needed to carry out center activities. An infrastructure of resources and personnel is required to support collaboration with partners and joint community mobilization efforts. (See Appendix 3, Glossary of Terms, for an

operational definition). Applicants should have the capacity to: Establish and maintain relationships with partners; facilitate the establishment and maintenance of the center's community committee(s); and collaborate with partners on the planning and implementation of core research, dissemination, training, and mobilization efforts. To assure that applicants have this capacity, applicants should:

(i) Describe the plan for establishing or maintaining the center's community committee(s). (See Appendix 3, Glossary of Terms for additional information regarding the center community committee.) This plan should include, at a minimum, the following: The intended composition and membership of the committee and how the constituents reflect the defined community; the proposed mission and role for the committee in the center's planning and activities, consistent with the logic model; a process for developing or refining guidelines for the community committee over the first year of the funding period; a plan for communication between the community committee and the center staff. Applicants must provide evidence of commitment and cooperation of current and potential members of the center's community committee (*e.g.*, letters of support, memorandums of understanding, or examples of prior collaboration.)

(ii) Identify and describe other partners such as local and state health departments, youth violence prevention organizations, community groups and agencies, youth organizations, and academic units. At a minimum, applicants need to briefly describe: Past partners, new partners, and proposed partners; the proposed methods for establishing and maintaining these partnerships, including how the lessons learned from previous partnerships will be applied to the proposed methods; and the partners' involvement in the center's proposed activities. In this section, applicants should specifically address the partners' role in developing this proposal and partners' expectations about their roles in the planning and implementation of the center's activities.

(iii) Provide evidence of commitment and cooperation of current and potential partners (*e.g.*, letters of support, memorandums of understanding, and examples of prior collaborations).

2. *Surveillance and Research Core:* Applicants need to describe and develop the infrastructure of resources and personnel required to support surveillance and research in the center.

Applicants need to enhance surveillance efforts and conduct research, as described below:

(a) *Surveillance:* Applicants should document experience in successfully developing, implementing and evaluating community level surveillance efforts in the last five years and describe plans to develop and/or enhance surveillance systems to be able to measure the problem of youth violence as well as determine impact of Center activities and research in the defined community. Applicants should address how your system will: Measure youth violence patterns in the defined community; be used to guide planning and evaluation of youth violence programs (*e.g.*, determine in what components and areas where prevention efforts are making a difference); and advance the public health research related to youth violence. All proposed surveillance activities should include an appropriate translation and dissemination plan. To assure that applicants have this capacity, applicants should, at a minimum: Document experience in successfully developing, implementing and evaluating community level surveillance efforts in the last five years.

(b) *Research:* Applicants should describe center capacity to: Establish a five-year research agenda; conduct core research and other prevention research as described in the research agenda; and effectively collaborate with partners in the identification, planning, implementation, and dissemination of core research. To assure that applicants have this capacity, applicants should, at a minimum: Document experience in successfully conducting, evaluating, and publishing youth interpersonal violence prevention research in the past five years; and describe community-based youth interpersonal violence prevention research activities and provide evidence of community involvement in those activities; and describe experience in conducting community-based participatory research in the past five years.

Applicants should describe (the core elements of) a five year research agenda, including a description of the core youth interpersonal violence prevention research project(s), and smaller studies and seed projects, as described below. The research projects and the agenda should reflect the potential for a center with a clear mission that promotes multidisciplinary collaboration and career development. The research agenda must represent more than an interesting collection of projects. Research projects must be interdependent (materials, results, data, or methodologies are shared among the projects), interrelated (each project must have goals and objectives that focus on the common theme), and multidisciplinary (representing different scientific backgrounds, training and expertise). Centers must develop research projects on youth interpersonal violence prevention with a conceptual focus on the defined community and that provide evidence of the potential for meaningful inter-disciplinary collaboration, and that respond to the NCIPC Research Agenda. Clear definitions of procedures used to select proposed and future projects are required.

The core research project should address the following types of applied interpersonal youth violence prevention research articulated in the NCIPC Research Agenda and that furthers the center's work in the defined community: intervention research, which examines the efficacy, effectiveness, economic efficiency of strategies, programs and policies in reducing or preventing youth interpersonal violence; and dissemination and dissemination implementation research (which includes research on the targeted distribution of information to a specific audience; and research on the use of strategies to introduce or change evidence-based youth interpersonal violence prevention interventions in specific settings).

Applicants should also demonstrate the links to the community within which the research is framed, documenting appropriate levels of support and collaboration. If the research agenda is also supported by non-ACE Program funding sources, identify the other funders.

The types of research projects centers are expected to carry out are listed below:

(i) Core research projects are the larger scale projects with annual budgets exceeding 150,000 a year, including direct and indirect costs, and lasting up to five years. These projects typically will test hypotheses and employ more sophisticated methodologies and/or larger sample sizes than small studies. Core research projects require an RO1 level summary as described in PHS 398 (Revised 5/01 and updated 6/28/02) guidelines.

(ii) Small studies of 25,000–150,000 a year, including direct and indirect costs, for one to three years duration, might be extensions of seed projects, either further developing methods or hypotheses in preparation for a larger investigation, or might be stand alone investigations sufficient to yield results

worthy of publication in a peer-reviewed journal and/or a technical report for a legislative body, governmental agency or youth violence prevention organizations.

(iii) Seed projects, under 25,000 require a short write-up describing the youth interpersonal violence prevention context of the study, the objective, the design, the setting and participants, the intervention being addressed, main outcome measurements, expected results, timelines, costs.

The applicant should use the following template to describe each proposed research project:

- Title of the project.
- Project Director/Lead Investigator for the project.
- Institution(s)/partners involved in the project.
- Categorization of the type of research (such as, but not exclusively, intervention, dissemination, and dissemination-implementation research).
- Relationship of the project to the center's mission and health priorities.
- Relationship of the project to local youth interpersonal violence prevention priorities, HHS objectives (*e.g.*, Healthy People 2010), and NCIPC Research Agenda.
- Indication of whether the project is new or ongoing. (If ongoing, describe the prior work on this project.)
- Evidence of community participation in the planning, implementation, and evaluation of the project. Describe how the center will collaborate with partners on refining and developing the research methodology, recruiting of research participants, and reporting and disseminating research findings.
- Summary of the research project:

(i) Background
(ii) Importance
(iii) Relevance to the defined community.
(iv) Integration into 5 year research agenda
(v) Goals and objectives
(vi) Proposed timeframe for the project
(vii) Setting and context
(viii) Methods and measures
(ix) Study participants and recruitment strategy. Provide evidence that the recipient (or a collaborating partner) has access to the study population and that the participation by the study population will be adequate to test hypotheses.
(x) Expected outcomes
(xi) Communication and dissemination

Data Sharing and Release: Describe plans for the sharing and release of data, if applicable (See AR–25 for additional information).

3. *Outreach and Education Core:* To ensure that applicants have the capacity to achieve the outreach and education program objectives, applicants should describe the following:

(a) *Community Mobilization:* Applicants need to describe a draft plan for community mobilization. Applicants should describe the infrastructure of resources and personnel to support community mobilization activities in the center and to develop and implement a community mobilization plan involving the primary community the center's activities will serve. For a definition of Community Mobilization and Community Mobilization Plan (CMP), see Appendix 3, Glossary of Terms. The two overriding goals of a community mobilization plan should be to: enhance the community's capacity to address the problem of youth violence and prevent or reduce youth violence. (For additional Guidance on how to develop a CMP, see: *http://www.phppo.cdc.gov/dphsdr/documents/MAPPone_pager.doc* and *http://mapp.naccho.org/mapp_introduction.asp*).

Applicants should have the capacity to: establish a five-year community mobilization plan (CMP); conduct community mobilization activities as required in the CMP; and effectively collaborate with partners in the identification, planning, implementation, and evaluation of the CMP. In addition, the CMP should provide evidence that applicant or their collaborating partners have access to the defined community population, and that the participation by the defined community population will be adequate to develop, implement and evaluate the plan.

To assure that applicants have this capacity, applicants should at a minimum:

(i) Provide evidence of having identified youth interpersonal violence prevention priorities, including disparities, within the defined community and of having identified them in collaboration with community partners.

(ii) Document experience in successfully developing, conducting, and evaluating community mobilization activities in the past five years.

(iii) Describe how the CMP helps fulfill the center's mission. If the community mobilization efforts are also supported by non-ACE Program collaborations, identify the other funders.

(iv) Describe the center's draft five-year CMP, including the goals and objectives. The applicant should use the following template and provide information to describe the community mobilization plan:

- Title of the plan;
- Core staff and community partners;
- Institution(s)/partners involved in the project;
- Indication of whether the community mobilization plan is new or ongoing. (If ongoing, describe the prior work on this plan.)
- Describe how the center will collaborate with partners: In the refinement of the CMP, in the development of the community mobilization methodology, for community recruitment, to report and disseminating information and activities, and to evaluate CMP outcomes.
- Summary of the Community Mobilization Plan.

This should include:

(i) Background;
(ii) How the plan furthers the defined community youth violence prevention needs, and priorities;
(iii) Describe how the CMP is integrated into the center's five-year research agenda and the centers mission;
(iv) Goals and objectives;
(v) Proposed timeframe for the plan;
(vi) Setting and context;
(vii) Methods and measures;
(viii) Community definition, participation and recruitment strategy;
(ix) Expected outcomes;
(x) Communication, dissemination, and evaluation.

(b) *Communication and Dissemination Activities:* Applicants should outline how they will develop a communication plan and describe the communication and dissemination infrastructure and activities to be carried out to further the program goals. Applicants should have the capacity to: disseminate research by making its findings, methods, and tools available; keep stakeholders (*i.e.*, researchers, practitioners, community members, and policymakers) abreast of the center's accomplishments; produce products that reflect research progress and results, and participate in coordinated activities with other ACEs and their collaborating partners (*e.g.*, state/local health departments, community groups, and youth violence prevention research and practice organizations) to facilitate linkages among ACEs and national/state/local partners to ensure National Program objectives are being achieved. To assure that applicants have this capacity, applicants should, at a minimum:

(i) Outline how a communication plan will be developed that defines and

describes how the center's communication and dissemination activities will be integrated into the center's activities, including the research agenda.

(ii) Address how the center will work with collaborators and other partners to extend the center's reach; how the center's activities and research will affect youth violence prevention policies impacting their community; and how other potential outcomes through communication and dissemination efforts will be identified.

(iii) Describe the methods the center will use to translate, communicate, and disseminate its products and other information. Address how the center will produce, translate and distribute publications and materials such as scientific papers, conference reports, newsletters, and educational and training materials; plan proposed meetings, personal interactions, and sharing of information with collaborators for the development of long-term partnerships; provide electronic dissemination of products and other information through websites and any other means; and develop media releases and statements, or pursue opportunities for media coverage.

(iv) Describe the center's infrastructure of resources and personnel that will support the identified communication and dissemination activities. At a minimum, describe the center's ability to: disseminate community-based youth violence prevention research in public health, allied disciplines and the constituent communities/stakeholders; translate the content of the center's activities for different audiences; develop a plan that reflects the community's youth demographic and cultural profile; and access personnel and resources, as applicable for layout and design, web site construction, photography, proofreading, and other development and production activities.

(c) *Training, Technical Assistance and Mentoring:* Applicants should describe the center's draft plan for providing training, technical assistance, and mentoring, and the infrastructure of resources and personnel required to support training, technical assistance, and mentoring of practitioners, researchers, students, community members, and other partners, as applicable. Applicants should have the capacity to assess, plan, implement, and evaluate training, technical assistance, or mentoring activities. Applicants, at a minimum, should address the following:

(i) Describe the center's assets or needs assessment (past, current, or proposed) for training, technical assistance, and mentoring. Explain collaboration with partners in the assets and needs assessment.

(ii) Describe the center's draft plan for providing training, technical assistance, and mentoring. This plan should include: goals and objectives; partner collaboration; and how the plan reflects the mission of the center and the assets and needs assessment described above. Describe how any lessons learned from prior training; technical assistance and mentoring activities during the past five years will be applied to the proposed plan. Additionally, describe training facilities and resources (*e.g.*, ability to print materials, use video and computer equipment, and develop Web sites).

(iii) Describe the opportunities and quality of the career development and mentoring plan for the junior investigators in the center. Applicants should describe the feasibility and potential for junior investigators to gain research experience in youth violence affecting at-risk populations.

The narrative should be no more than 100 pages (8.5″ × 11″), double-spaced, and printed on one side only, with one-inch margins on all sides and unreduced 12-point font. Appendices must be hard copy documents (*i.e.*, no audiovisual materials or posters).

In order to facilitate the preparation and review of the application, the application components should be organized according to the Table of Contents listed below. The table of contents below supersedes the instructions contained in the PHS 398.

- Detailed Budget for the Initial Budget for the Entire Proposed Period for Each Project.
- Budget for the Entire Proposed Period of Support for the Entire Proposed Center.
- Detailed Budget Justification for Each Proposed Project/Activity for the Initial Budget Period.
- Biographical Sketch-Principal Investigator/Program Director.
- Other Biographical Sketches.
- Other Research Support.
- Executive Summary with Overall Goals and Objectives of the Center.
- Center Logic Model.
- Application Narrative:

Overall Description of the Proposed Center.

Statement on the Institutional Commitment to the Proposed Center.

Performance/Accomplishments in Last Project Period (Current Centers).

Past Performance/Accomplishments Relevant to Proposed Center.

Administrative and Infrastructure Core: Defined Community; Evaluation; Infrastructure; Collaborations/Partnerships.

Surveillance and Research Core: Surveillance Projects; Core Research Projects; Seed Projects.

Outreach and Education Core: Community Mobilization; Communication and Dissemination Activities: Training, Technical Assistance, and Mentoring.

The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application.

IV.3. Submission Dates and Times

LOI Deadline Date: December 22, 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 10, 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 send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the PHS 398 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 application. If you have a question about the receipt of your application, first contact your courier. CDC will not notify you by mail upon receipt of your application, but if you still have any questions, contact the PGO–TIM staff at: 770–488–2700. Before

calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board 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 must 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 copy of your application by mail or express delivery service to: Technical Information Management CE05–018, 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 objectives identified in 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 shall be submitted with the application and shall 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 the following items in the determination of scientific merit.

1. *Administrative and Infrastructure Core* (Total: 150 points)

(a) Defined Community (25 points). To what extent does the applicant adequately define and describe the primary community that the center's activities serve, such as: (i) The size of the defined geographic or non-geographic community, (ii) characteristics such as demographic make up, socioeconomic, and cultural characteristics, (iii) levels of youth violence and a description of the prevalent risk and protective factors, (iv) the youth violence prevention and public health infrastructure, including levels of organization and support for interpersonal youth violence prevention and community health interventions, (v) community assets and history of ''community participation, (vi) existing health, education, community, justice and other local policies related to youth violence prevention. How well does the applicant describe the center links to the defined community and document appropriate levels of engagement and collaboration?

(b) Program Evaluation (50 points). To what extent does the applicant: (i) Appropriately describe the center-level logic model and provide a narrative description of components of the logic model, (ii) sufficiently describe and justify how each component of the center's logic model relates to or differentiates from the national ACE Program conceptual framework, (iii) describe relevant evaluation experiences and expertise as it relates to conducting an evaluation of the applicant's center, (iv) articulate a five-year evaluation plan for evaluating the critical components of the center's logic model, including the goals and objectives, and (v) illustrate how the center's evaluation plan is related to the national ACE Program evaluation activities, which includes annual reporting on national performance indicators.

(c) Infrastructure (25 points). To what extent does the applicant: (i) Provide a detailed organizational chart that represents the center's activities, (ii) describe how the organizational structure facilitate the center's activities, (iii) describe the positions needed to accomplish the center's goals and objectives, (iv) propose a staffing plan with the required experience, expertise, and percentage of effort among the center's leadership, research, evaluation, communications, training, information management, and fiscal administration staff to accomplish its proposed goals and objectives, (v) explain how it will increase its capacity over time, (vi) demonstrated the applicant's commitment to the center (*e.g.*, facilities, technological resources, etc.)and adequate university commitment to establish and maintain an identity for the proposed center.

Is sufficient documentation of institutional endorsement of the proposed five-year research and community mobilization plans offered, including: (i) Letters of commitment from senior institutional officials from both collaborating institutions, (ii) letters of support that fully address and support the priorities and objectives of the center.

(d) Collaborations/Partnerships (50 points). To what extent does the applicant: (i) Describe the center's community advisory committee, particularly its initial mission, roles, composition, and plans for developing or refining guidelines, (ii) provide letters of support or other evidence from these partners of active participation in this collaboration that fully address and support the priorities and objectives of the center, (iii) outline the past and newly established partnerships, the roles of these partners, and the methods for establishing and maintaining the partnerships, and (iv) articulate the proposed activities with the identified partners?

2. *Surveillance and Research Core* (Total: 200 Points)

(a) Surveillance (50 points). To what extent does the applicant: (i) Describe the establishment and/or enhancement of surveillance system(s) to be able to measure the problem of youth violence

in the chosen community, (ii) address how these efforts will lead to a better understanding of factors influencing youth violence prevention, and (iii) include an appropriate translation and dissemination plan for the proposed surveillance activities?

(b) Research (150 points). To what extent does the applicant:

(i) Describe the research project(s) linkage to the center's mission and priorities identified in the logic model and the NCIPC Research Agenda? Outline a conceptual research framework, design, methods, and analyses that are well integrated, and appropriate to the aims of the center? Propose research project(s) that address an important research objective related to youth interpersonal violence prevention and disparities in the defined community? Explain how this research will lead to a better understanding of factors influencing youth violence prevention in the defined community?

(ii) Articulate the significance of the proposed research, and describe the effect of these studies on the concepts or methods that drive the youth violence prevention field? Employ novel concepts, approaches or methods in youth violence prevention research? Explain how the research challenges existing paradigms or develops new methodologies or technologies? Propose research of sufficient originality, novelty, and innovation to make it highly relevant to the overall goals and objectives of the national ACE Program? Acknowledge potential problem areas and consider alternative interdisciplinary approaches? Offer clear evidence of significant interdisciplinary interactions in the conception, design, and proposed implementation of the research?

(iii) Document collaboration with the community, providing clear evidence of community participation in developing and conducting the project? Demonstrate community support and liaison, and evidence of interaction with, and participation of community members and community leaders in the development and conduct of the research? Propose a design that demonstrates sensitivity to cultural and socioeconomic factors in the community?

(iv) Demonstrate success in conducting, evaluating, and publishing previous community-based youth violence prevention research in the past five years? Demonstrate a reasonable degree of community-based participatory research, and being trained and well-suited to carry out this work? Propose work appropriate to the experience level of center researchers?

(v) Describe a scientific environment conducive to the probability of success of the research to be conducted? Propose studies that take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Provide evidence of adequate institutional and community support?

(vi) Provide sufficient evidence regarding the development and implementation of effective communication channels between researchers and community members? Address plans for useful and successful practical dissemination of project activities and findings within the defined community?

3. *Outreach and Education Core* (Total: 150 Points)

(a) Community Mobilization Plan (50 points). To what extent does the applicant's draft plan:

(i) Enhance the community's capacity to address the problem of youth violence and improve the health of the community, by preventing or reducing youth violence, particularly among those most affected?

(ii) Present clear goals, objectives and activities that address the youth violence problem in the defined community? Address and take into account community contextual factors (*i.e.* socioeconomic and cultural context, level of youth violence, public health and youth violence prevention infrastructure, history of community participation and existing support for the issue)?

(iii) Offer adequate evidence of center experience in successfully developing, conducting, evaluating, and publishing on community mobilization activities in the past five years? Delineate community involvement in the development of the CMP?

(iv) Address the development and review of the plan (*i.e.* describe external review and critique mechanisms)?

(b) *Communications and Dissemination* (50 points). To what extent does the applicant: (i) Address the diversity or special needs of the community or subgroups, (ii) describe communications and dissemination activities that are integrated into the center's goals and objectives, (iii) anticipate how these activities will have an effect on local policies, and other potential outcomes, (iv) describe how the proposed methods for the center's communication and dissemination activities to help accomplish the center's goals and objectives, and (v) describe an adequate infrastructure of resources and personnel to support the center's communication and dissemination activities?

(c) *Training, Technical Assistance and Mentoring* (50 points). To what extent does the applicant: (i) Describe and justify the center's assets or needs assessments for training, technical assistance, or mentoring activities, (ii) outline a suitable training, technical assistance, and mentoring plan that reflects the mission of the center and the assets or needs assessment described above, (iii) describe the opportunities and quality of the career development and mentoring plan for the junior investigators in the center.

Protection of Human Subjects from Research Risks: Does the applicant 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, Minorities in Research: Does the applicant adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? (See Attachment 1, AR–2 for more information). 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.

V.2. Review and Selection Process

Applications will be reviewed by the Procurement and Grants Office (PGO) staff for completeness, and for responsiveness by the National Center for Injury Prevention and Control. Incomplete applications and applications that are non-responsive will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

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 National Center for Injury Prevention and Control 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.
- Receive, if deemed to have the highest scientific merit, a second programmatic level review by the Science and Program Review Subcommittee (SPRS) of the Advisory Committee for Injury Prevention and Control (ACIPC).

Applications which are complete and responsive may be subjected to a preliminary evaluation (streamline review) by an external peer review committee, the National Center for Injury Prevention and Control 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 shall 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 a peer review conducted by the IRG. All applications will be reviewed for scientific merit in accordance with the review criteria listed above. Applications will be assigned a score based on a scoring system of 100–500 points, in which the strongest applications will receive a higher point score, and the weakest applications a lower point score.

The Science and Program Review Subcommittee (SPRS) of NCIPC's Advisory Committee for Injury Prevention and Control (ACIPC) will conduct the secondary review. The 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 Director for Science (ADS) or their designees will attend the secondary review in a similar capacity as the ACIPC Federal agency experts to assure that research priorities of the announcement are understood and to provide background regarding current research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered would be the same as those considered by the SPRS.

The 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:

- Merit (as determined by peer review)
- Availability of funds
- Geographic diversity
- Consistency with research priorities in CDC's Injury Research Agenda

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

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

VI.2. Administrative and National Policy Requirements 45 CFR Part 74 and Part 92

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

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–9 Paperwork Reduction Act Requirements. Projects that involve the collection of information from ten or more persons and that are funded by cooperative agreements will be subject to review and approval by the Office of Management and Budget (OMB).
- 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–21 Small, Minority, Women-Owned Businesses.
- AR–22 Research Integrity.
- AR–23 States and Faith-Based Organizations.
- AR–24 Health Insurance Portability and Accountability Act Requirements.

Additional information on AR–1 through AR–24 can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm*.

- 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 the CDC with original, plus two hard copies of the following reports:

1. Interim progress report (PHS 2590, OMB Number 0925–0001, rev. 5/2001) 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 status and final performance reports, no more than 90 days after the end of the project period.

4. Additional requested information: The applicant will be responsible for submitting information on program performance. This will include, but is not limited to the following: providing information on all projects (*i.e.*, core projects, special interest projects, and other funded projects) and products (*i.e.*, publications, presentations, surveys, etc.); providing semi-annual updates on information requested by the program and provided in the application; and collaborating with the national ACE Program on the continued development and improvement of a reporting system.

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

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, telephone: (770) 488–2700.

For questions about scientific/research program technical issues contact: Thomas Vogelsonger, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway, NE. MS K–02, Atlanta, GA 30341, telephone: (770) 488–4823, FAX: (770) 488–1662, e-mail: *TVoglesonger@cdc.gov*.

For questions about peer review issues, contact: Gwen Cattledge, Ph.D., Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K–02, Atlanta, GA 30341, telephone: 770–488–1430, e-mail: *GXC8@cdc.gov*.

For financial, grants management, or budget assistance, contact: James Masone, Contracts Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, telephone: 770–488–2736, FAX: 770–488–2671, e-mail: *ZFT2@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.''

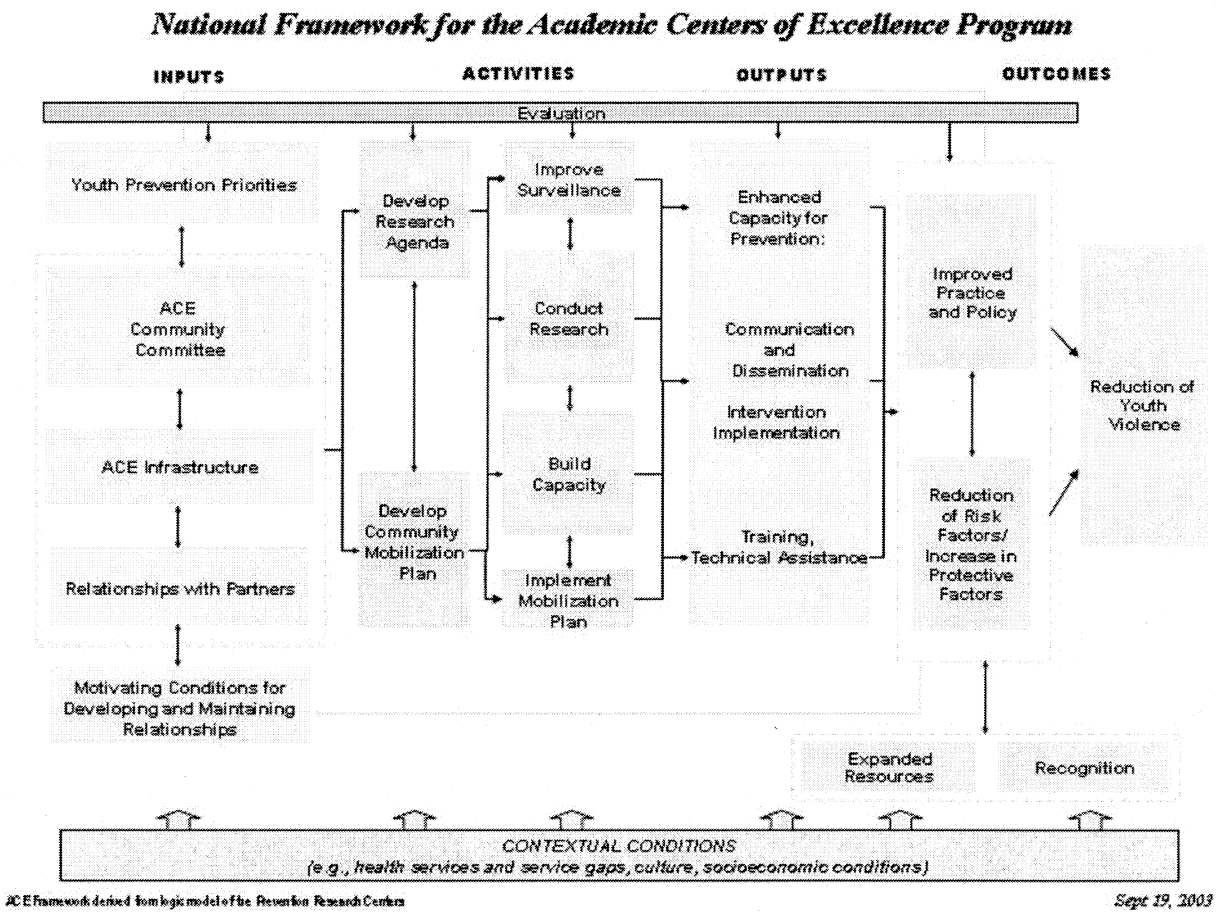
To locate the following attachments/appendices for this program announcement go to CDC Web site.

Dated: November 10, 2004.

William P. Nichols,

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

Appendix 1



Narrative Description of the Conceptual Framework for the National Academic Centers of Excellence for Youth Violence Prevention (ACE) Program

The conceptual framework for the National Academic Centers of Excellence for Youth Violence Prevention (ACE) Program was developed to describe the future orientation of the program, its activities and the outcomes it expects to achieve. The national framework or logic model was created through a participatory process involving a diverse set of national, state, and local stakeholders and ACE grantees, and draws heavily from the Centers for Disease Control (CDC) Prevention Research Centers (PRC) model. The elements of the framework and its linkages are consistent with the Congressional language authorizing the establishment of the program, and CDC research policies.

This model serves as a planning mechanism for center in guiding their activities during the 5-year grant period. The framework identifies the inputs, activities, outputs, and outcomes common to all ACE's and shows the expected relationships among these components. The diagram of the framework summarizes how the program is presumed to work. Although the boxes of the framework are shown in a linear fashion, the relationships among them are expected to be complex, interactive, and recursive over time.

The national framework does not imply that one size fits all. To reflect uniqueness, each ACE should create their own logic model by tailoring the national framework or logic model to the center's specific activities and goals. The national framework cannot show the emphasis an individual ACE may place on one type of activity over another. The time required to achieve different outputs may vary among ACEs and depends on many factors, such as the type of research conducted and other activities undertaken, the amount of resources devoted to activities such as dissemination, and contextual factors. Thus, the framework does not specify the time it may take to achieve outputs or outcomes.

Diagram Note: The size of the boxes in the diagram depends on the amount of text in each box and does not denote the relative importance of a specific element.

Inputs. The first column of the conceptual framework, inputs, refers to the assumptions underlying a program and the infrastructure that must be in place before a program can be implemented. The four inputs the framework captures are described below.

Youth Prevention Priorities. Each ACE is established to address youth interpersonal violence prevention priorities and enhance knowledge of effective youth violence prevention in a defined community. Community is defined as a group of people who share some or all of the following: geographic boundaries; a sense of membership; culture and language; common norms, interests, or values; and common health risks or conditions. [IOM 2002] [CDC/ATSDR Principles of Community Engagement] It refers to a population

that has a distinct identity. It can mean residents of a geographic area, be that a catchement area, neighborhood, school district, city, county or region within a county. It can be used with a modifier or clause to describe a non-geographically based subgrouping such as, but not exclusively: a community of youth violence prevention workers, a community of health professionals, or an ethnic or language community. The ACE program focuses its research activities on the violence prevention issues of high priority to the defined community and that address state or national youth violence prevention priorities, and such gaps identified in the Research Agenda of CDC's National Center for Injury Prevention and Control and those stated in *Healthy People 2010*.

Diagram Note: Two-way arrows connect the youth violence prevention priorities and box and the next three combined input boxes.

ACE Community Committee. CDC will require each ACE to form or work with an existing ACE Community Committee. This group comprises members of the ACE's defined community and adult and youth representatives of agencies and organizations that serve the Center's designated community. The Community Committee participates in the Center's organization, research, or other activities. Committee members typically represent an identified group or population and participate in the committee in order to provide the perspective and knowledge of a designated population or group to the activities of the Center.

The inputs provided by an ACE Community Committee to the ACE include guidance, advice on ACE agendas and plans, expertise, contacts, essential information about the designated community as well as intangible benefits. Some ACE's may wish to form additional advisory groups, as needed, such as a policy board, a youth advisory board, or advisory committees for individual research projects. The decision to form these additional groups depends on the needs of the ACE and the community.

ACE Infrastructure. Before conducting specific youth violence prevention research, projects, and health promotion activities, an ACE must have the necessary internal infrastructure. This infrastructure includes the necessary human resources capacity to recruit faculty with the necessary core expertise, diversity and sensitivity. It also includes the necessary evaluation expertise as well as faculty and staff who have the requisite multidisciplinary expertise to implement ACE projects and activities and experience working with the community, and expertise for evaluating the implementation of the ACE's activities and to assess the ACE's outcomes and accomplishments. The Centers are mandated to create an infrastructure that facilitates initiatives that involve researchers and practitioners from varied disciplines, and collaboration across university centers. Finally, ACE capacity requires communication and data systems that enable and facilitate work, and administrative capacity (*e.g.*, financial resources).

Relationships with Center Partners. Each ACE is also expected to establish and maintain center partnerships with institutions such as state and local health, education, justice departments, other university partners, other ACEs, Injury Control Research Centers (ICRCs), Prevention Research Centers, national youth violence prevention organizations, and CDC. Partnerships are intended to strengthen the ACE's surveillance, research, training, mentoring, community mobilizing and dissemination activities in its identified community. Partners can collaborate with the ACE in designing and conducting research and other ACE projects and in disseminating research findings, which are expected to help facilitate the translation of public health research and related activities to practice and policy.

Diagram Note: A dotted box around these three inputs indicates that the ACE, its community, and its external partners are the major stakeholders; they collaborate with each other to implement the ACE Program. The inputs for Community Committee, Infrastructure, and Relationships with Partners also have two-way arrows touching each other. A two-way arrow connects the combined boxes for these inputs with that for the next input. One-way arrows also connect the three boxes to the first two program activities.

Motivating Conditions for Developing and Maintaining Relationships. The conceptual framework also recognizes the conditions motivating the development and maintenance of relationships with community partners and others. These conditions may include trust and tangible or intangible benefits (such as access to expertise or acceptance by a community) and sharing of resources gained from the partnership. These conditions may influence a partner's willingness to form a relationship with the ACE, the nature and strength of the relationship, and an ACE's ability to sustain the relationship over time.

Activities. The second and third columns of the conceptual framework capture the activities that include: developing a research agenda; developing a community mobilization plan; conducting surveillance, research, building capacity and implementing the community mobilization plan. (Multi-sectoral and multi-disciplinary collaboration and dissemination are inputs and outputs, respectively.)

Research Agenda. An ACE is encouraged to engage stakeholders within its defined community in developing an overall research plan, identifying research priorities, selecting research projects, recruiting research participants, refining research methods, developing interventions, conducting research, and reporting and disseminating research findings. ACE Centers are charged with establishing a five-year research agenda with tied to one or more HHS objectives, *Healthy People 2010, NCIPC Research Agenda, Guide to Community Prevention Services* and local youth violence prevention research priorities.

Community Mobilization Plan. ACEs are charged with the development and implementation of a five-year community mobilization or action plan (in collaboration with the Community Committee). Further, the development of a Community Mobilization Plan should be tied to the Research Agenda with an identified relationship to one or more youth violence prevention priorities.

Diagram Note: A two-way arrow connects the boxes for the development of the research agenda and the development of the community mobilization plan. One-way arrows connect the boxes for the mobilization plan and the research agenda to the next set of activities. A two-way arrow connects the research agenda and the mobilization plan as these processes should inform one another.

Conduct Core Activities:

- *Surveillance.* This core area includes the gathering, analysis and interpretation of surveillance data to enable the defined community with whom the ACE is working to better measure the problem of youth violence, and accurately reflect trends in the target community and the greater community. All Surveillance activities proposed should include an appropriate translation and dissemination plan.
- *Research.* The research conducted should be informed by local priorities, the NCIPC Research Agenda, and contribute to new methods of study, understandings of, or ways to prevent youth interpersonal violence. In addition, ACEs may conduct research funded by other federal agencies and by state agencies, community-based

organizations, and foundations. All research is expected to be conducted using sound research methods that further the field of youth interpersonal prevention research. All research proposed under the ACE program should include an appropriate dissemination plan.

• *Build Capacity.* ACEs are also charged with developing a five-year plan to train, provide technical assistance to, or mentor health professionals, researchers, practitioners, students, community members, and others. These activities, which are expected to be developed in collaboration with the recipients, may cover a range of topics, including youth violence prevention best practices, community building, research, and evaluation as well as other needs identified by ACE partners. ACEs may also train and provide technical assistance to community partners on implementing specific prevention and health promotion interventions, including effective practices.

• *Implement the Community Mobilization Plan.* ACE's are expected to form, nurture and advance partnerships with the community designed to implement evidence-based strategies or promising programs. Community implementation efforts can include convening stakeholders—including the most affected—helping to organize across different sectors, fostering strategic alliances, and strengthening community bonds; assessing community resources; mapping community assets; and enabling a fuller understanding of and response to the nature and dynamics of local violence.

Diagram Note: Two-way arrows connect these four core activities to one another. One-way arrows connect surveillance, research, capacity building, and community implementation to the three outputs (intervention implementation, communication and dissemination, and training and technical assistance).

Outputs. The fourth column captures outputs generated or produced as a result of program activities. Through the process of planning, carrying out public health-related youth violence prevention activities, and the promotion of collective action, it is expected that the professionals and community residents will gain increased skills and confidence (or a greater sense of ''efficacy'') enhancing its capacity for prevention. Enhanced capacity includes an improved ability on the part of agencies and organizations to implement and make well-reasoned decisions about effective violence prevention programs and services. It also includes enhanced academic infrastructure in service-learning, student practicum opportunities. This capacity combines a community's and a university's commitment, resources, and skills to respond to public health needs and priorities. Another aspect of enhanced capacity is the development of skilled ''violence preventers.'' This term includes not only professionals—both developing new skills for those entering the field as young researchers/practitioners and improving existing skills of current violence prevention workers—but also providing skills to youth, parents, and volunteers. Community stakeholders who collaborate with the ACE's in implementing research projects and who participate in ACE-sponsored training and technical assistance improve their skills as a result. The selected measurable products, or outputs, of these activities and processes are described below.

Communication and Dissemination. The communication and dissemination of research and evaluation findings are another type of output. These findings are typically published in peer-reviewed journals, books, and technical reports. They also may be presented to various audiences at professional conferences, community meetings, or other settings, and reported to the media. Findings from research conducted with a community should be shared with community partners and with other ACE's.

Intervention Implementation. Many ACEs develop, implement and test violence prevention strategies, programs and interventions in a community, encouraging the implementation of evidence-based strategies or promising programs. A program may rely on a curriculum, a manual, or a particular prevention strategy or health promotion tool, which is packaged and made available to interested organizations or individuals.

Training, Technical Assistance. ACE's training or technical assistance activities can include an assessment of the skills acquired, number of trainees and recipients of technical assistance, the number and duration of training or technical assistance events, and the satisfaction of participants with the training or technical assistance they received.

Diagram Note: Together, all the output boxes connect to a combined set of two outcome boxes through a one-way arrow. These two outcomes connect to each other by two-way arrows.

Outcomes. The last column of the conceptual framework shows the outcomes, or the intended effects of cumulative program activities over time.

Improved Practice and Policy. One expected outcome of the ACE Centers' activities is the uptake of interventions and improved youth interpersonal violence prevention practice and policies. Surveillance, research, capacity building, and community implementation activities conducted by the ACEs are expected to be translated into community practice or policies adopted by local and state health departments, schools, other public agencies (*e.g.*, recreation departments, housing authorities), and community-based organizations. Over time, these interventions and policies may be disseminated beyond an ACE's defined community and receive widespread use.

Reduction of Risk Factors/Increase in Protective Factors. Another expected outcome of the ACE Centers' activities is the reduction of risk factors/increase of protective factors in the community, a result of the uptake of improved violence prevention practice and policies.

Expanded Resources and Recognition. An ACE may be able to expand its resources beyond the core funding, research faculty, and initial organizational and agency partnerships that were formed when it first received CDC funding. An ACE may also gain recognition within a community and the nation for expertise in a particular field or area of youth interpersonal violence prevention, and for its partnerships.

Diagram Note: One set of dotted lines surrounds the boxes for the two outcomes. A second set surrounds the two additional boxes below it (expanded resources and recognition). These groupings show the potential relationships with other components of the framework with which they are logically connected or which they are likely to influence or be influenced by. The outcomes flow back through motivating conditions and up the input column. They also connect to youth violence prevention agendas and down the input column. A one-way feedback arrow also extends from the outcomes back to the inputs of youth violence prevention priorities and motivating conditions for developing and maintaining relationships.

Contextual Conditions. The box across the bottom of the conceptual framework is for contextual conditions, which are socioeconomic, political, and cultural factors external to the ACE Program that may not be within its control but which may influence the implementation of activities and achievement of outcomes. Note that these conditions may relate to all components of the framework.

Evaluation. Evaluation is a part of the ACE Program (noted at the top of the

framework) that extends across all the inputs, activities, outputs, and outcomes, except for the ultimate outcome. The arrow to each column signifies that the ACE Program will evaluate aspects of each component, guided by performance monitoring and evaluation questions. Many factors can contribute to the final outcome, and empirical data demonstrating a causal link between proposed program activities and improvements in community health are lacking. Therefore, the ACE Program will not evaluate the ACEs' effect on violence-induced death, disability and injury among adolescents, but will evaluate program effect on improved practice and policy, and reduction of risk factors/increase in protective factors.

The ACE Program evaluation will collect data that may include information about how inputs are being used to shape the ACE Program, which activities are undertaken by the collective program, the quality of the activities, and the specific outcomes the program is accomplishing. CDC, ACEs, and other stakeholders can use evaluation findings for many purposes, including modifying program activities or enhancing and strengthening relationships with community partners. Evaluation findings also provide information that can be shared with external stakeholders, can help document the program's value, and may provide justification for continuing or increasing program funding.

Appendix 2.—List of Indicators for the National Academic Center of Excellence on Youth Violence Prevention Program

1. Evidence of ACE Community Committee participation in the determination of ACE violence prevention priorities.
2. Level of ACE Community Committee members satisfaction with participation.
3. Evidence of establishment of partnerships and maintenance of partnerships.
4. Establishment of a Community Mobilization Plan.
5. Establishment of a Research Agenda.
6. Evidence of community improvements in the ability to monitor and describe youth violence.
7. Extent to which the research portfolio is contributing to new methods of study, understandings of, or ways to prevent youth violence.
8. Evidence that the ACE Center is mobilizing the community to implement evidence-based strategies or promising programs.
9. Evidence of a communication and dissemination plan, developed with input from key partners.
10. Evidence of producing and disseminating research findings through peer-reviewed publications, and educational or technical materials.
11. Evidence of a plan for training researchers, practitioners and community members.
12. Extent to which center activities and evidence-based strategies have been translated into the outcomes listed.
13. Extent to which researchers, practitioners, and community members have been trained, mentored, or provided technical assistance in youth violence prevention.
14. Evidence of new grants, contracts or other resources awarded to the ACE Center or its partners.

Appendix 3.—Glossary of Terms

Youth Interpersonal Violence

Youth interpersonal violence is defined as: The intentional use of physical force or power, threatened or actual, exerted by or against children, adolescents or young adults, ages 10–24, which results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation. Youth interpersonal violence encompasses peer and community violence between individuals or groups who may or may not know each other. This form of violence frequently takes place outside the home, in the streets, or in institutional settings, such as schools, workplaces, and prisons. Youth violence also encompasses violence that occurs between youth and family members and other intimate relations. The nature of violence can be physical, sexual, and psychological. (Adapted from WHO Report on Violence and Health, 2002). [Adapted from WHO Report on Violence and Health. To access the Report go to: *http://www.who.int/violence_injury_prevention/violence/world_report/en/*].

Community

Community is defined as a group of people who share some or all of the following: geographic boundaries; a sense of membership; culture and language; common norms, interests, or values; and common health risks or conditions. [IOM 2002] [CDC/ATSDR Principles of Community Engagement].—It refers to a population that has a distinct identity. It can mean residents of a geographic area, such as a catchment area, neighborhood, school district, city, county or region within a county. It can be used with a modifier or clause to describe a non-geographically based sub-grouping such as, but not exclusively: A community of youth violence prevention workers, a community of health professionals, or an ethnic or language community.

Community Mobilization

Community mobilization is a process through which action is stimulated by a community itself or by others, that is planned, carried out, and evaluated by a community's individuals, groups, and organizations on a participatory and sustained basis to reduce or prevent youth violence, and improves health. [Save the Children/Health Communication Partnership]

Community Mobilization Plan (CMP)

The plan is a general description of how you and your partners intend work with a particular community to mobilize around youth violence prevention. A mobilization plan defines the overall goals and objectives and identifies a process that will help interested communities achieve them, not to determine specific community actions or activities. The two overriding goals of community mobilization are to: 1. Enhance the community's capacity to address the problem of youth violence; 2. Prevent or reduce youth violence, thereby improving the health of the community.

The goal of a community mobilization plan must be related to local youth violence prevention priorities. Where communities perceive a pressing youth violence prevention need, communities themselves may define the goal. Alternatively, ACEs and their stakeholders may identify a goal based on an analysis of community health indicators (*e.g.*, frequency and severity of specific health problems and feasibility to address them). [Health Communication Partnership]

Community Participation

The active involvement of the members of a community in the planning, creation, operation, evaluation, dissemination and oversight of an initiative or project.

Community Committee

A group of individuals that represent groups and organizations within the Center's designated community. The Community Committee participates in the Center's organization, research, or other activities. Committee members typically represent an identified group or population and participate in the committee in order to provide the perspective and knowledge of a

designated population or group to the activities of the Center.

CDC will require each ACE to form an ACE Community Committee. This group should comprise members of the ACE's defined community and adult and youth representatives of agencies and organizations serving that community. The inputs provided by an ACE Community Committee to the ACE include guidance, advice on ACE agendas and plans, expertise, contacts, essential information about the designated community as well as intangible benefits. Some ACE's may wish to form additional advisory groups, as needed, such as a policy board, a youth advisory board, or advisory committees for individual research projects. The decision to form these additional groups depends on the needs of the ACE and the community.

Center Partnerships

Each ACE is also expected to establish and maintain center partnerships with institutions such as state and local health, education justice departments, other university partners, other ACEs, Injury Control Research Centers (ICRCs), Prevention Research Centers, national youth violence prevention organizations, and CDC. Partnerships are intended to make the ACE's surveillance, research, training and mentoring, community mobilizing and dissemination activities relevant to its identified community. Partners can collaborate with the ACE in designing and conducting research and other ACE projects and in disseminating research findings, which are expected to help facilitate the translation of public health research and related activities to practice and policy.

Community-Based Participatory Research (CBPR)

Scientific inquiry conducted in communities in which community members, persons affected by condition or issue under study and other key stakeholders in the community's health have the opportunity to be full participants in each phase of the work (from conception—design—conduct—analysis—interpretation—conclusions—communication of results).

Definition Developed by Inter Agency Working Group for CBPR, Convened by NIEHS, NIH, August 2, 2002

According to the CARE–CDC Health Initiative, A Model for Global Participatory Research, in community-based participatory research, the definition of scientific rigor is broadened to encompass community participation in decisionmaking at every phase of the research process: defining the problem, setting goals, selecting methods, interpreting data, and recommending policy. Essential to this philosophical construct is the assurance of quality decision making throughout the research process. In the document Building Community Partnerships in Research, participatory research is described as the gold standard toward which all federally funded research should aspire. (5)(p7). [Building Community Partnerships in Research: Recommendations and Strategies. Executive Summary. Washington, DC: U.S. Dept of Health and Human Services; April 7, 1998.]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0494]

Guidance for Industry on Changes to an Approved New Drug Application or Abbreviated New Drug Application; Specifications—Use of Enforcement Discretion for Compendial Changes

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Changes to an Approved NDA or ANDA; Specifications—Use of Enforcement Discretion for Compendial Changes.'' This guidance informs new drug application (NDA) and abbreviated new drug application (ANDA) holders of FDA's plan to use enforcement discretion with regard to the regulation on changes to an approved application. This regulation describes the filing requirement that a relaxation of acceptance criteria or deletion of a test to comply with an official compendium must be reported in a changes-being-effected-in-30-days supplement (CBE–30). FDA does not intend to take enforcement action if manufacturers continue to submit such changes in their annual reports. The use of enforcement discretion will give the agency time to clarify that some of these types of postapproval changes can be submitted in an annual report, rather than in a CBE–30. The agency intends to clarify this issue in an upcoming revision to a guidance for industry.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David J. Cummings, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5187.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 8, 2004 (69 FR 18728), FDA published a final rule entitled ''Supplements and Other Changes to an Approved Application.'' In the same issue of the **Federal Register** (69 FR 18768), FDA announced the availability of the guidance for industry entitled ''Changes to an Approved NDA or ANDA'' (the changes guidance). Under § 314.70(c)(2)(iii) (21 CFR 314.70(c)(2)(iii)) of the final rule, the relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements must be submitted as a CBE–30 (see section VIII.C.1.e of the changes guidance).

FDA is issuing this guidance to explain that it is using enforcement discretion with regard to § 314.70(c)(2)(iii) to address concerns raised by stakeholders. FDA plans to clarify that some of these types of changes can be submitted in an annual report, instead of a CBE–30 supplement, in a revision of the guidance for industry entitled ''Changes to an Approved NDA or ANDA; Questions and Answers.''

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in