DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Community-Based Interventions for Alcohol-Impaired Driving

Announcement Type: New.

Funding Opportunity Number: CE05–024.

Catalog of Federal Domestic Assistance Number: 93.136.

Dates:

Letter of Intent deadline: December 20, 2004.

Application deadline: February 7, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under section 301(a) [42 U.S.C. 2410(a)] of the Public Health Service Act, and section 391(a) [42 U.S.C. 280 b(a)] of the Public Service Health Act, as amended.

Background: Prevention of alcohol-impaired driving is among the most important strategies to reduce motor vehicle-related injuries and deaths. ''Healthy People 2010: Health Objectives for the Nation'' has set objectives of reducing alcohol-related motor vehicle fatalities to no more than 4.0 per 100,000 persons and reducing alcohol-related motor vehicle injuries to no more than 65 per 100,000 persons, from 1998 baselines of 5.9 and 113, respectively. To meet these objectives, the nation must reduce alcohol-impaired driving, community by community.

According to health promotion theory, a multifaceted approach to the prevention of alcohol-impaired driving is desirable due to the potential for different interventions to work synergistically. The implementation and evaluation of multifaceted community-based interventions that target alcohol-impaired driving is necessary to measure the effectiveness of such efforts and provide data to inform future efforts.

Purpose: This research study is a cooperative agreement that seeks to evaluate interventions to decrease alcohol-impaired driving in community settings and the resulting deaths and injuries. This announcement is appropriate for organizations that are currently conducting research of multifaceted, community-based intervention that targets alcohol- and/or motor vehicle-related injuries.

Funds will be provided to: (1) Evaluate the supplementary benefits from adding one or more strategies to reduce alcohol-impaired driving to an existing multifaceted community-based program to prevent alcohol- and/or motor vehicle-related injuries; or (2) evaluate the results of an existing, effective multifaceted community-based intervention to reduce alcohol-impaired driving when applied to another community with different demographic characteristics.

This project addresses the ''Healthy People 2010'' focus areas of Injury and Violence Prevention and Adverse Consequences of Substance Use and Abuse.

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

- Conduct a targeted program of research to reduce injury-related death and disability.

Outcomes should also be in alignment with the following research priorities in transportation safety from the National Center for Injury Prevention and Control (NCIPC) Research Agenda:

- Evaluate strategies to implement and disseminate known, effective interventions to reduce alcohol-impaired driving and test the effectiveness of new, innovative strategies.
- Develop methodologies for and evaluate the effectiveness of various means to translate transportation safety research findings into public policy.

The grantees are expected to widely disseminate the outcomes through traditional mechanisms, such as professional and peer-reviewed journal publications.

Research Objectives

- Nature of the research problem—

Research is needed to measure the effectiveness of multifaceted community-based interventions in reducing alcohol-impaired driving.

- Scientific knowledge to be achieved through research supported by this program—

This research will help develop a better understanding of the extent to which: (1) Specific components of multifaceted interventions contribute to their effectiveness in reducing alcohol-impaired driving, and (2) outcomes generalize across communities with different demographic characteristics.

Objectives of This Research Program

- To assess the effectiveness of either: (1) Adding one or more strategies to reduce alcohol-impaired driving to an existing multifaceted community-based intervention to reduce alcohol- and/or motor vehicle-related injuries; or (2) implementing an existing community-based intervention targeting alcohol-impaired driving that has evidence of effectiveness in the current community to a separate community that has different demographic characteristics.
- To obtain process-related information regarding barriers to implementation of such interventions and the means to overcome them. This process and outcome information will be used to inform future community-based programs to reduce alcohol-impaired driving.

The goals of the announcement can be accomplished in either of two ways. First, an existing community-based intervention can be supplemented by adding strategies targeting alcohol-impaired driving. For example, sobriety checkpoints could be integrated into a multifaceted intervention targeting high-risk alcohol consumption and related injuries. Alternatively, an existing community-based intervention targeting alcohol-impaired driving that has evidence of effectiveness in the current community could be implemented in a separate community that has different demographic characteristics. For example, an intervention that is underway in an urban community could be expanded to a rural community.

Research and Experimental Approaches To Achieve the Objectives

The preferred approaches to assessing the effectiveness of the interventions include quasi-experimental research designs using time series data, comparison communities, or both (as appropriate given pre-existing evaluation plans). Baseline measures of variables related to alcohol-impaired driving should be collected before implementation of the intervention or addition of the new intervention strategy(s). Direct assessment of driver blood alcohol content levels in roadside surveys is the preferred outcome variable. However, other acceptable outcome variables would be self-reported alcohol-impaired driving from appropriately designed telephone surveys or crashes likely to be alcohol-related, such as single-vehicle nighttime crashes.

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

For effective interventions, it is possible to do cost-effectiveness studies. To be comparable to other cost effectiveness studies, they should follow

the guidelines in the following references:

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

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

Activities

Awardee activities for this program are as follows:

1. This study will require the existence of a core coalition (or coalitions) that would ideally include representatives from the following groups:

- Community leaders, groups, and organizations (*e.g.*, policy makers, safety advocates, schools, youth organizations, local media, health care providers, and social service agencies)
- Public health departments
- Transportation and traffic safety agencies
- Governors' highway safety representatives
- Law enforcement
- Academic evaluation experts

2. Applicants will be expected to: (1) Incorporate one or more additional strategies related to alcohol-impaired driving into an existing community-based intervention; or (2) expand an existing, effective multifaceted community-based intervention to prevent alcohol-impaired driving to a community with different demographic characteristics.

Examples of effective or innovative strategies that the applicant is encouraged to consider include:

- Sobriety checkpoints to reduce alcohol-impaired driving. Key components of the intervention: Officer training in appropriate practices; implement or increase the frequency of sobriety checkpoints (or roving patrols if checkpoints are not feasible); develop a strategy for publicizing checkpoints through earned media (*e.g.*, news stories) and/or paid media.
- Server intervention training. Key components of the intervention: Face-to-face training regarding legal obligations and methods of preventing patron intoxication for servers and other staff; training and/or on-site consultation with managers on responsible practices.
- Community-wide designated driver promotion. A key component of the intervention: A substantial majority of drinking establishments in the community offer and promote incentives for designated drivers.

Applicants who choose to incorporate additional strategies into an existing community-based intervention may select other promising or innovative interventions to prevent alcohol-impaired driving. Justification for the selected interventions should be provided in the application. Applicants who choose to expand an existing community-based intervention to an additional community must provide some evidence of the effectiveness of the existing intervention and issues related to generalizability in the new community.

Applicants will also be expected to collect outcome data on the effectiveness of interventions in reducing alcohol-impaired driving, such as changes in alcohol-related crashes, injuries, or deaths, and perform process evaluations from community-based activities designed to reduce alcohol-impaired driving.

CDC Activities for This Program Are as Follows:

1. Assist to provide up-to-date scientific information, technical assistance, and guidance in project matters, where and when requested.

2. Provide technical assistance and guidance in analysis and dissemination of results, including assistance in the preparation of manuscripts, where and when requested.

3. Assist in ensuring human subjects assurances and protections are in place as necessary.

4. Monitor and evaluate the scientific and operational accomplishments of the project, as needed. This may be accomplished through periodic site visits, telephone calls, electronic communication, and bi-annual reports.

5. Convene meetings with recipient for the exchange of information.

6. Review and approve, if needed, IRB protocols initially, and assist in filing IRB continuation applications, at CDC, on at least an annual basis until the research study, including analysis, 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: E11.

FY Funds: 2005.

Approximate Total Funding: $350,000 (This amount is an estimate and is subject to availability of funds.)

Approximate Number of Awards: One.

Approximate Average Award: $350,000 (This amount is for the first 12-month budget period and includes both direct and indirect costs. Approximately $1,050,000 total is available over the entire three years of the project period.)

Floor of Award Range: None.

Ceiling of Award Range: $350,000 (This ceiling is for the first 12-month budget period and includes both indirect and direct costs.) If the budget proposed exceeds this amount, it will not be eligible for review, and will be discarded.

Anticipated Award Date: September 1, 2005.

Budget Period Length: 12 months.

Project Period Length: Three years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit and for profit organizations and by governments and their agencies, such as:

- Federally recognized Indian tribal organizations
- State, local, and tribal public health departments
- Transportation and traffic safety agencies
- Research Institutions
- Colleges and Universities
- Private non-profit organizations
- For-profit organizations

A Bona Fide Agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a state application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

Eligible applicants will be limited to those currently conducting a multifaceted community-based intervention trial targeting alcohol-impaired driving, other high-risk alcohol use, or motor vehicle-related injuries. Due to the time and expense involved in building community coalitions, implementing interventions, and planning evaluations, the available funds are not sufficient to adequately support a trial for which these steps have not already taken place.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

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

Special Requirements

- If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.
- Late applications will be considered non-responsive. *See* section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- In order to plan the application review more effectively and efficiently, CDC requires that you submit a Letter of Intent (LOI) to apply for this program. *See* ''IV.3. Submission Dates and Times'' for more information on deadlines.
- The applicant should provide evidence that the performing organization is conducting a multifaceted community-based intervention to prevent alcohol-and/or motor vehicle-related injuries that could feasibly be expanded according to the terms of this RFA. This expansion could be accomplished either by adding a new alcohol-impaired driving strategy to the intervention, or by implementing the intervention in an additional community.
- The applicant should provide evidence of effective and well-defined collaborative relationships within the performing organization and among the coalition members that will ensure implementation of the proposed activities. Documentation, such as letters of collaboration, describing the specific commitments and responsibilities that will be undertaken by the coalition members and community organizations must be included in an appendix.
- The applicant and its collaborative team should provide evidence of prior experience in implementing and evaluating community-based interventions. This experience must be documented by including publications such as those from peer-reviewed journal articles or technical reports in the appendix of the application.
- The recipient should provide evidence of access to target populations and experience with accessing community leaders and community-level groups.
- The applicant must provide a written evaluation plan for the existing community-based intervention that details how the added intervention strategies or site will be incorporated. This plan should include: (1) A list of outcome measures and the data source for each measure, and (2) baseline measurement results for each outcome variable.
- **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.

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

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

Principal investigators are encouraged to submit only one proposal in response to this program announcement. With few exceptions (*e.g.*, research issues needing immediate public health attention), only one application per principal investigator will be funded under this announcement.

IV. Application and Submission Information

IV.1. Address To Request Application Package

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

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html.* If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770/488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Application Submission Letter of Intent (LOI)

Your LOI must be written in the following format:

- Maximum number of pages: 2 pages
- Font size: 12-point unreduced
- Single-spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

Your LOI must contain the following information:

- Descriptive title of the proposed research
- Name, address, E-mail address, telephone number, and FAX number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this Announcement

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 research plan should address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

This announcement uses the non-modular budgeting format.

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

prevention. The narrative portion of the application must not exceed 25 double-spaced pages with unreduced 12-point font.

The research plan (abstract) should answer the following questions:

- Does the research plan state the hypothesis?
- Does the research plan describe the objectives?
- Does the research plan state the importance of the research and how it is innovative?
- Does the research plan outline the methods that will use to accomplish the goals?
- Is the language of the research plan simple and easy to understand for a broad audience?

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Letter of Intent (LOI): December 20, 2004.

CDC requires that you submit a LOI if you intend to apply for this program. Although the LOI will not be evaluated, and does not enter into review of your subsequent application, failure to submit a timely LOI will preclude you from submitting an application.

Application Deadline Date: February 7, 2005.

Explanation of Deadlines: **LOIs and applications must be received in the CDC procurement by 4 p.m. Eastern time on the deadline date.** If you submit your LOI and application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

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

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770/488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed Federal assistance applications. You should contact your State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

IV.5. Funding Restrictions

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

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board approvals are in place.

Sufficient time and resources should be devoted to preparing an acceptable IRB package. Funds for human subjects recruitment and human subjects research will be withheld until appropriate IRB approval has been obtained.

- Reimbursement of pre-award costs is not allowed.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to:

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

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

Application Submission Address: Submit the original and one hard copy of your application by mail or express delivery service to: Technical Information Management—[#CE05–024], CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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

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

Address for U.S. Postal Service Mail: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control, 4770 Buford Hwy, NE., Mailstop K–62, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

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

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

that by its nature is not innovative, but is essential to move a field forward.

The Review Criteria Are as Follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Will study advance scientific knowledge of how to implement and evaluate community-based interventions for preventing alcohol-impaired driving.

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? To what extent do the applicant's work plan and timetable include:

- The identification of representatives to be named as members of the coalition, including a description of the areas of expertise covered by each; the specific roles and responsibilities of each in implementing this project; methods for making decisions; etc.
- Memorandum of agreement and understanding or letters of support from these collaborating organizations as an appendix, and the extent to which these letters indicate that the applicant and the other collaborating organizations have established a ''working partnership'' which specifies the active roles each will have in the study.
- Plans for collecting or obtaining and analyzing baseline (pre-intervention) and follow-up data for the measures of effectiveness.
- A description of the process used in selecting the intervention strategies to be implemented or sites to be added.
- A description of proposed methods for implementing and evaluating the additional intervention strategies or sites.
- Initial plans to rigorously evaluate the interventions, including appropriate measures of effectiveness. Measures should be objective and quantifiable and include measures of alcohol-impaired driving and/or alcohol-related crashes.
- Availability of adequate facilities and appropriately trained staff to carry out this activity.
- Acknowledgement of potential problem areas and plans to consider alternative tactics.

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? If new, innovative strategies to reduce alcohol-impaired driving are tried, what is the rationale for selecting them and the likelihood they will succeed?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? Does the principal investigator, co-investigator, or subcontractor have extensive experience in implementing community-based research and programs? Does the Principal Investigator have the authority to manage the project?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed study take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? To what extent have the applicant and proposed collaborators documented:

- Their history and current capacity to provide a leadership function in convening and facilitating the work of the coalition.
- Their history and current capacity to provide a leadership function in the implementation and evaluation of the selected alcohol-impaired driving prevention activity.
- Their history and current capacity to present findings at national conferences and prepare peer-reviewed manuscripts.
- Their organizational capacity to realize the objectives of the cooperative agreement.
- Their management operation, structure and/or organization. An organizational chart of the applicant's organization should be included as an appendix. Additionally, the applicant should include within their management plan the specific role and mechanisms to be established to ensure effective coordination, communication and shared decision making among the involved agencies/organizations.
- A staffing plan for the project, noting existing staff as well as additional staffing needs. The responsibilities of individual staff members including the level of effort and allocation of time for each project activity by staff position should be included.
- Resumes, biosketches, and/or position descriptions (*i.e.* for current staff, in-kind, and proposed positions to be funded under this cooperative agreement) should be included as an appendix. This should include the use of consultants, as appropriate.
- A continuation plan in the event that key staff leave the project, how new staff will be smoothly integrated into the project, and assurances that resources will be available when needed for this project.
- Previous experience of project staff to submit required reports on time.

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

- Has the investigator developed an adequate plan for disseminating the study results?

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? This will not be scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Applicants should consider the need for IRB submissions early in the grant cycle to avoid delays and restrictions on funds.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Inclusion of Children as Participants in Research Involving Human Subjects:

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

All investigators proposing research involving human subjects should read the ''NIH Policy and Guidelines'' on the inclusion of children as participants in research involving human subjects that

is available at: *http://grants.nih.gov/grants/funding/children/children.htm.*

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by the National Center for Injury Prevention and Control. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified 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 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.
- Applications deemed to have the highest scientific merit will receive a second programmatic level review by the Science and Program Review Subcommittee (SPRS) of the Advisory Committee for Injury Prevention and Control (ACIPC).

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

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee SEP, recommendations by the external 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 SEP. A committee of reviewers with appropriate expertise will review all applications for scientific merit using current National Institutes of Health (NIH) criteria (a scoring system of 100—500 points) to evaluate the methods and scientific quality of the application. All categories are of equal importance, however, the application does not need to be strong in all categories to be judged likely to have a major scientific impact.

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

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

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

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

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

V.3. Anticipated Announcement of Award Dates

September 1, 2005

VI. Award Administration Information

VI.1. Award Notices

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

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

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

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

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.

- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–7 Executive Order 12372.
- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities.
- AR–14 Accounting System Requirements.
- AR–22 Research Integrity.
- AR–23 States and Faith-Based Organizations.
- AR–24 Health Insurance Portability and Accountability Act Requirements (HIPAA).

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

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of Effectiveness.

f. Dissemination activities.

g. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

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

VII. Agency Contacts

We encourage inquiries concerning this announcement.

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

For scientific/research issues, contact: L.J. David Wallace, MS, Injury Prevention Specialist, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02, Atlanta, GA 30341; Telephone: 770/488–4712, E-mail: *Dwallace2@cdc.gov.*

For questions about peer review, contact: Gwendolyn Cattledge, PhD., Scientific Review Administrator, Associate Director for Extramural Research, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02; Atlanta, GA 30341; Telephone: 770/488–1430, E-mail: *gxc8@cdc.gov.*

For financial, grants management, or budget assistance, contact: James Masone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: 770/488–2736, 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.''

Dated: November 10, 2004.

William P. Nichols,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10052 and CMS–370, 377, 378, R–54]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (new) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419; *Use:* Information is necessary to determine eligibility of medical devices for establishment of additional device categories for payment under