voluntarily agreed for a period of three (3) years, beginning on October 30, 2003:

(1) To exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That her participation in any PHS-supported research will be conditioned on an appropriate plan of supervision of her duties (Supervision Plan) as follows: (i) Any institution that submits an application for PHS support for a research project in which Ms. Creek's participation is proposed or anticipated must concurrently submit a Supervision Plan to the funding agency for approval; and (ii) any institution using Ms. Creek in any capacity in PHS-supported research must submit a Supervision Plan to the funding agency for approval. The Supervision Plan must be designed to ensure the scientific integrity of her research contribution. A copy of the Supervision Plan must also be submitted to ORI by the institution. Ms. Creek agreed that she will not participate in any PHS-supported research until the Supervision Plan has been submitted to ORI.

**FOR FURTHER INFORMATION CONTACT:** Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443–5330.

**Chris B. Pascal,**

*Director, Office of Research Integrity.*

[FR Doc. 03–29866 Filed 12–1–03; 8:45 am]

**BILLING CODE 4150–31–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Findings of Scientific Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Office of Research Integrity (ORI) and the Acting Assistant Secretary for Health have taken final action in the following case:

*Lajuane Woodard, University of Maryland, Baltimore:* Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB Report), the respondent's admission of responsibility, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Lajuane Woodard, former contractual employee, Department of Pediatrics at UMB, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant 2 R01 MH54983, entitled ''Effectiveness of Standard versus Embellished HIV Prevention.''

Specifically, PHS found that Ms. Woodard engaged in scientific misconduct by fabricating interview records for the Focus on Teens HIV Risk Prevention Program for one interview claimed to have been performed in June 2001.

Ms. Woodard has entered into a Voluntary Exclusion Agreement (Agreement ) in which she has voluntarily agreed for a period of three (3) years, beginning on October 30, 2003:

(1) To exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That her participation in any PHS-supported research will be conditioned on an appropriate plan of supervision of her duties (Supervision Plan) as follows:

(i) Any institution that submits an application for PHS support for a research project in which Ms. Woodard's participation is proposed or anticipated must concurrently submit a Supervision Plan to the funding agency for approval; and

(ii) Any institution using Ms. Woodard in any capacity in PHS-supported research must submit a Supervision Plan to the funding agency for approval. The Supervision Plan must be designed to ensure the scientific integrity of her research contribution. A copy of the Supervision Plan must also be submitted to ORI by the institution. Ms. Woodard agreed that she will not participate in any PHS-supported research until the Supervision Plan has been submitted to ORI.

**FOR FURTHER INFORMATION CONTACT:** Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443–5330.

**Chris B. Pascal,**

*Director, Office of Research Integrity.*

[FR Doc. 03–29865 Filed 12–1–03; 8:45 am]

**BILLING CODE 4150–31–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Youth Violence Prevention Through Community-Level Change

Announcement Type: New.

Funding Opportunity Number: 04054.

Catalog of Federal Domestic Assistance Number: 93.136.

**Key Dates**

*Letter of Intent Deadline:* January 2, 2004.

*Application Deadline:* February 17, 2004.

**I. Funding Opportunity Description**

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

*Purpose:* The purpose of the program is to announce the availability of fiscal year (FY) 2004 funds for a cooperative agreement program for the evaluation of community-level interventions to reduce youth violence.

This program addresses the ''Healthy People 2010'' focus area Injury and Violence Prevention.

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

*Research Objectives:* Youth violence has been linked to a variety of factors, including individual, family, community, and societal characteristics. While much research has been conducted on interventions with individuals and families, less often have interventions focused on variables at the broader community level.

There are a number of characteristics of communities that increase the probability of violence. Rates of violence are high in areas that have large concentrations of poor and unemployed people, crowded housing, residential instability, family disruption, illegal drug distribution and sales, diminished private economic activity, and limited positive opportunities for youths and adults (Reiss & Roth, 1993; Sampson & Lauritsen, 1994). Rates of violence are also high in neighborhoods where there is low community participation, disorganization, and a lack of cohesion. People living in these types of communities tend to be socially isolated and exhibit lower levels of attachment to the community—factors that also

limit their ability to supervise and control adolescent peer groups, especially gangs (Sampson & Lauritsen, 1994).

Research funded under this announcement is expected to address this important gap in the prevention literature (*i.e.,* the implementation and evaluation of interventions that are designed to modify the above types of community characteristics). The ultimate aim of such an approach is to assess whether interventions designed to change community structures and social processes can reduce rates of youth violence in communities.

At a minimum, competitive applicants will provide theoretical rationale and empirical evidence in support of the specific intervention proposed, and will conduct a rigorous evaluation of the intervention.

*Activities*

Awardee activities for this program are as follows:

- Develop and finalize the research design and methodology, data collection measures, and analyses, and disseminate study results through publications and presentations.
- Develop a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.
- Obtain approval of the study protocol by the recipient's local IRB.
- Collect data on the costs associated with implementing and evaluating the intervention.
- Conduct one reverse site visit to meet with CDC staff in Atlanta on an annual basis.
- Complete all required reports as specified under ''Reporting Requirements''.
- Provide a protocol/manual documenting the intervention and the manner in which it was implemented, including any information on activities occurring prior to the start of the intervention, such as stakeholder meetings, collaboration building, or focus groups.

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

CDC Activities for this program are as follows:

- Provide scientific and programmatic consultation. CDC will collaborate with project staff on decision-analyses, programmatic issues, and dissemination of the study results in publications and presentations.
- Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is finished.
- CDC staff will monitor and review scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.

**II. Award Information**

*Type of Award:* Cooperative Agreement.

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

*Fiscal Year Funds:* 2004.

*Approximate Total Funding:* 1,000,000.

*Approximate Number of Awards:* Two.

*Approximate Average Award:* 500,000.

*Floor of Award Range:* $250,000.

*Ceiling of Award Range:* $500,000.

*Anticipated Award Date:* September 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Four years.

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

**III. Eligibility Information**

*III.1. Eligible applicants:* Applications may be submitted by public and private nonprofit and for profit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- For profit organizations.
- Small, minority, women-owned businesses.
- Universities.
- Colleges.
- Research institutions.
- Hospitals.
- Community-based organizations.
- Faith-based organizations.
- Federally recognized Indian tribal governments.
- Indian tribes.
- Indian tribal organizations.
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
- Political subdivisions of States (in consultation with States).

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

*III.2. Cost Sharing or Matching:* Matching funds are not required for this program.

*III.3. Other Eligibility Requirements:* 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.

If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet submission requirements. The following are applicant requirements:

- A principal investigator who has documented prior training and experience in conducting efficacy and effectiveness trials.
- A principal investigator who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
- Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing violence prevention research in peer-reviewed journals.
- Effective and well-defined working relationships within the performing organization and with outside entities, which will ensure implementation of the proposed activities.
- The overall match between the applicant's proposed research objectives and the program priorities as described under the heading, ''Funding Priority''.
- The requested funding amount is within the award range of $250,000–$500,000.
- Principal investigators (PI's) are encouraged to submit only one proposal in response to this program announcement. With few exceptions (*e.g.*, research issues needing immediate public health attention), only one application per PI will be funded under this announcement.

*4. Individuals Eligible To Become Principal Investigators*

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

**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.

## IV. Application and Submission Information

*IV.1. Address to Request Application Package:* To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

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

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

*IV.2. Content and Form of Application Submission*

*Letter of Intent (LOI):* CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, your LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review. Your LOI must be written in the following format:

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

Your LOI must contain the following information:

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

*Application:* Follow the PHS 398 application instructions for content and formatting of your application (See Attachment 1 of this announcement for guidance on how to complete Form 398 for this Program Announcement). The Program Announcement Title and number must appear in the application. For further assistance with the PHS 398 application form, 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 must include a research plan with your application. The research plan should be no more than 25 pages (8.5″ x 11″ in size), single-spaced, printed on one side only, with one-inch margins on all sides, and unreduced 12-point font. Your application will be evaluated on the criteria listed under Section V. ''Application Review Information'', so it is important to follow them, as well as the Research Objectives and the Administrative and National Policy Requirements (ARs), in laying out your research plan. Your research plan should address activities to be conducted over the entire project period. The research plan should consist of the following information:

1. *Abstract:* It is especially important to include an abstract that reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

2. *Program Goals and Objectives:* Describe the goals and objectives the proposal is designed to achieve in the short and long term. Specific research questions and hypotheses should also be included.

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

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

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

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

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

8. *Data sharing and release:* Describe plans for the sharing and release of data (See AR–25 for additional information).

9. *Project Budget:* Provide a detailed budget for each activity undertaken, with accompanying justification of all

operating expenses that is consistent with the stated objectives and planned activities of the project.

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 in item 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.*

*IV.3. Submission Dates and Times*

*LOI Deadline Date:* January 2, 2004.

*Application Deadline Date:* February 17, 2004.

*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 application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application 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. 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 application deadline. This will allow time for applications to be processed and logged.

4. *Intergovernmental Review of Applications:* Executive Order 12372 does not apply to this program.

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

*Funding Priority*

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

- Strategies to increase social integration and cohesion by increasing community participation as well as formal and informal social support.
- Strategies to improve the physical and social characteristics of neighborhoods through environmental design changes (*e.g.*, Crime Prevention Through Environmental Design).
- Strategies to improve financial, housing, and/or employment issues in impoverished areas.
- Efforts to deconcentrate areas with high rates of poverty and violence.
- Strategies to increase formal and/or informal supervision of youth (such as providing structured or unstructured activities to youth during non-school hours, or encouraging adults to monitor youths' activities in their neighborhood).
- Strategies to reduce community density and availability of alcohol and drugs.
- Strategies to modify social norms about violence or other related issues and values.

*Funding Preferences*

Funding preference will be given to proposals that:

- Propose more stringent and rigorous evaluation designs, including: experimental and quasi-experimental designs with appropriate baseline/pre-intervention data, post-intervention data, and at least one follow-up data collection point; data from at least one comparison or control community; and data collected from multiple sources.
- Measure outcomes and impacts at the neighborhood or community level and focus on risk and protective factors specific to that level of intervention. Examples could include: police records of neighborhood or community arrests for violent crimes, violent school incidents (aggregated to the school or system level), hospital or Emergency Room data aggregated by neighborhood or community, or intake rates for juvenile detention facilities.
- Propose a conceptual model or theory of change for how the intervention will produce the intended reductions in youth violence, and measure proposed mediators and moderators of program outcomes.
- Describe plans for ensuring that the intervention is implemented as it was designed (*i.e.*, intervention fidelity) and that the target community received or had access to the intervention (*i.e.*, program exposure).
- Propose data analytic plans that are appropriate to the intervention, research design and hypotheses, data collection measures, and project period, and that anticipate and evaluate the effect of threats to the internal and external validity of the specified research design.
- Target traditionally underserved communities.

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.

*6. Other Submission Requirements*

*LOI Submission Address:* Submit your LOI by express mail, delivery service, fax, or e-mail to: Robin Forbes, CDC, NCIPC, 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 five copies of your application by mail or express delivery service to: Technical Information Management—PA# 04054, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

**V. Application Review Information**

*V.1. Criteria*

You 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 goal 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 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 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 criteria are as follows:

*Significance:* Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

*Approach:* Are the conceptual framework, design, methods, and analyses adequately developed, scientifically rigorous, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and 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?

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

*Environment:* Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

*Additional Review Criteria:* In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score: Intervention: Is the potential effectiveness of the proposed intervention within the target community theoretically justified and supported with epidemiologic, methodological, and behavioral research? How feasible is the implementation of the intervention as proposed? Can the intervention reasonably be predicted to produce the expected reductions in youth violence? Is the setting of implementation appropriate?

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

*Inclusion of Women and Minorities in Research:* Does the application adequately address the CDC Policy requirements regarding the inclusion of woman, 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.

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) 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 PA will be subjected to a preliminary evaluation (streamline review) by a peer review committee, the Initial Review Group (IRG) convened by NCIPC, 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 or program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

1. 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 priority score based on the National Institutes of Health (NIH) scoring system of 100–500 points.

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

The secondary review committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and

to assure that unwarranted duplication of federally-funded research does not occur. The secondary review committee has the latitude to recommend to the NCIPC Director, to reach over better-ranked proposals in order to assure maximal impact and balance of proposed research. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in ''Healthy People 2010,'' the Institute of Medicine report, ''Reducing the Burden of Injury,'' and the ''CDC Injury Research Agenda.''

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the IRG, recommendations by the secondary review committee, ACIPC, consultation with NCIPC senior staff, and the availability of funds.

*Award Criteria:* Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

**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.

2. *Administrative and National Policy Requirements:* 45 CFR part 74 and part 92.

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

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–8 Public Health System Reporting Requirements
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR–14 Accounting System Requirements
- AR–15 Proof of Non-Profit Status
- AR–16 Security Clearance Requirement
- AR–21 Small, Minority, and Women-Owned Business
- AR–22 Research Integrity
- AR–23 States and Faith-Based Organizations
- AR–24 Health Insurance Portability and Accountability Act Requirements
- AR–25 Release and Sharing of Data

Starting with the December 1, 2003 receipt date, all NCIPC funded investigators seeking more than $250,000 in total costs in a single year are expected 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/release, including the timeliness and 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/release may also be appropriate in other sections of the application (*e.g.* background and significance, human subjects requirements, etc.). The content of the data sharing/release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing/release plan will not count towards the application page limit and will not factor into the determination scientific merit or priority scores. Investigators should seek guidance from their institutions, on issues related to institutional policies, 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 visiting the NCIPC Internet Web site at: *http://www.cdc.gov/ncipc/osp/sharing_policy.htm.*

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

*VI.3. Reporting:* You must provide CDC with an original, plus two 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. Additional Requested Information.

f. Measures of Effectiveness.

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**

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

For scientific/research program technical assistance, contact: Jennifer Wyatt, Behavioral Scientist, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K–60, Atlanta, Georgia 30341, Telephone: 770–488–4058, E-mail: *ANU1@cdc.gov.*

For questions about peer review, contact: Gwendolyn Cattledge, Scientific Review Administrator, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K–02, Atlanta, Georgia 30341, Telephone: 770–488–1430, E-mail: *gxc8@cdc.gov.*

For budget assistance, contact:

Nancy Pillar, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2721, E-mail: *nfp6@cdc.gov.*

Dated: November 25, 2003.

**Edward Schultz,**

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

[FR Doc. 03–29895 Filed 12–1–03; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003E–0253]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; LEXAPRO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined