products is entered into the catalog. This is a conservative assumption because the number of incremental additions to the catalog from year to year is likely to be much lower after initial start-up efforts have been completed. The total catalog disclosure burden for all industries covered by the Rule is 2,550 hours (150 sellers x 17 hours annually).

Estimated annual cost burden: ($8,353,641 in labor costs and $3,519,422 in capital or other non-labor costs).

Labor Costs: Staff derived labor costs by applying appropriate estimated hourly cost figures to the burden hours described above. In calculating the cost figures, staff assumes that test procedures are conducted by skilled technical personnel at an hourly rate of $20.00, and that recordkeeping and reporting, and labeling, marking, and preparation of fact sheets, generally are performed by clerical personnel at an hourly rate of $10.75.

Based on the above estimates and assumptions, the total annual labor costs for the five different categories of burden under the Rule, applied to all the products covered by it, is $8,353,641 (rounded to the nearest thousand), derived as follows:

Activity	Burden hours per year	Wage category hourly rate	Total annual labor cost
Testing	360,721	Skilled technical/$20	$7,214,420
Reporting	1,324	Clerical/$10.75	14,233
Recordkeeping	767	Clerical/$10.75	8,245
Labeling, marking, and fact sheet preparation	101,333	Clerical/$10.75	1,089,330
Catalog disclosures	2,550	Clerical/$10.75	27,413
			8,353,641

Capital or Other Non-Labor Costs: $3,519,000 (rounded), determined as follows:

Staff has examined the five distinct burdens imposed by EPCA through the Rule—testing, reporting, recordkeeping, labeling, and retail catalog disclosures—as they affect the 11 groups of products that the Rule covers. Staff has concluded that there are no current start-up costs associated with the Rule. Manufacturers have in place the capital equipment necessary—especially equipment to measure energy and/or water usage—to comply with the Rule.

Under this analysis, testing, recordkeeping, and retail catalog disclosures are activities that incur no capital or other non-labor costs. As mentioned above, testing has been performed in these industries in the normal course of business for many years as has the associated recordkeeping. The same is true regarding compliance applicable to the requirements for paper catalogs. Manufacturers and retailers who make required disclosures in catalogs already are producing catalogs in the ordinary course of their businesses; accordingly, capital cost associated with such disclosure would be minimal or nil. Staff recognizes that there may be initial costs associated with posting online disclosure, and it invites further comment to reasonably quantify such costs.

Manufacturers that submit required reports to the Commission directly (rather than through trade associations) incur some nominal costs for paper and postage. Staff estimates that these costs do not exceed $2,500. Manufacturers must also incur the cost of procuring labels and fact sheets used in compliance with the Rule. Based on estimates of 50,113,098 units shipped and 128,650 fact sheets prepared,[4] at an average cost of seven cents for each label or fact sheet, the total (rounded) labeling cost is $3,516,922.

William E. Kovacic,

General Counsel.

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BILLING CODE 6750–01–P

[4] The units shipped total is based on combined actual or estimated industry figures across all of the product categories, except for fluorescent lamp ballasts, lamp products, and plumbing products. Staff has determined that, for those product categories, there are little or no costs associated with the labeling requirements. The fact sheet estimation is based on the previously noted assumption that five percent of HVAC manufacturers produce fact sheets on their own. Based on total HVAC units shipped (10,291,965), five percent amounts to 514,598 HVAC units. Because manufacturers generally list more than one unit on a fact sheet, staff has estimated that manufacturers independently preparing them will use one sheet for every four of these 514,598 units. Thus, staff estimates that HVAC manufacturers produce approximately 128,650 fact sheets.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Grants for New Investigator Training Awards for Unintentional Injury, Violence Related Injury, Injury Biomechanics, and Acute Injury Care Research

Announcement Type: New.

Funding Opportunity Number: CE05–021.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates:

Letter of Intent (LOI) Deadline: December 6, 2004.

Application Deadline: February 2, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, and section 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 funds for grants for new investigator training awards in four research areas: unintentional injury prevention, violence-related injury prevention, injury-related acute care/mass trauma research, and injury-related biomechanics research. This program addresses the ''Healthy People 2010'' focus areas of Injury and Violence Prevention.

The purposes of this program are to:

- Solicit research applications that address the priorities reflected under the heading, ''Research Objectives''.
- Encourage professionals from a wide spectrum of disciplines to conduct research aimed at preventing and controlling injuries more effectively.
- Support injury research by new investigators who are doctoral-level graduates and who have not previously received injury-related CDC R49 or their equivalent grants.
- Build the scientific base for the prevention and control of unintentional- and violence-related injuries, disabilities, and deaths.

• Encourage qualified applicants who are beginning to focus on injury-related research.

The career development objectives of this program are to encourage scientists to develop independent research skills and to gain experience in advanced methods and experimental approaches in injury-related research. This program is also intended to jump start the careers of researchers in injury prevention and control by providing support for pilot studies, enhancements to existing studies, or other studies that will serve as a foundation for a career in injury prevention and control. Applicants are required to have a mentor with extensive injury research experience who will assist the applicant with scientific and career-related issues during the period of the award.

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

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

• Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence.

• Monitor and detect fatal and non-fatal injuries.

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

Background and Significance

Unintentional Injury Research

For the purposes of this program announcement, unintentional injuries are defined as unintentional damage to the body resulting from acute exposure to thermal, mechanical, electrical, or chemical energy or from the absence of such essentials as heat or oxygen.

Unintentional injuries continue to be a major public health problem. In 2000, 97,900 people died in the United States as a result of unintentional injuries. Someone dies every six minutes in the U.S. from causes such as motor vehicle crashes, falls, poisoning, drowning, fires and burns, pedestrians struck by vehicles, bicycle crashes, or choking and suffocation. In addition to deaths, injuries also constitute a significant cause of both permanent and temporary disability. In 2000, unintentional injuries resulted in an estimated 29.1 million emergency department visits and millions more seek treatment for injuries from health care professionals. In addition to the emotional costs of injuries, the financial costs of unintentional injuries are staggering: well over $200 billion a year in medical care, wage and productivity losses and employer costs alone. Unintentional injuries are not accidents, they are predictable and they are preventable.

Violence Related Injury Research

Deaths and injuries associated with interpersonal violence and suicidal behavior are also a major public health problem in the United States and around the world. In 2000, over 46,000 people died from homicide and suicide in the United States. Among 15 to 24 year olds, homicide and suicide ranked as the second and third leading causes of death. Violent deaths are the most visible consequence of violent behavior in our society. Morbidity associated with physical and emotional injuries and disabilities resulting from violence, however, also constitute an enormous public health problem. For every homicide that occurs each year there are over 100 nonfatal injuries resulting from interpersonal violence. For every completed suicide it is estimated that there are 20 to 25 suicide attempts. The mortality and morbidity resulting from violence are associated with a variety of types of violence including child maltreatment, youth violence, intimate partner violence, sexual violence, elder abuse, and self-directed violence or suicidal behavior.

Biomechanics Research

The field of biomechanics quantifies the response and tolerance of the human body to impact (*e.g.,* motor vehicle collisions, playground falls, and child battering) and addresses the underlying mechanisms of injury, the forces deforming the body and the physiologic effects of injury to infants, children, adults and the aged population. Based on interdisciplinary research, the engineering factors are determined that deform the body and the medical consequences are quantified that affect vital functions. This knowledge is used to modify the design of protective systems to improve safety. Improved safety systems protect an individual from impact forces that can injure, and they can include protective equipment (cycling helmets) and environments (playground surfaces), occupant restraints (airbags and safety belts), and policies (rules to minimize spearing in football). Biomechanical knowledge can also be used to improve post-injury outcomes through physiologic models to address emergency medical treatments, pharmacologic interventions and rehabilitation to advance recovery.

NCIPC's biomechanics program attempts to build on the basic knowledge of biomechanics and encourage interdisciplinary intervention-oriented injury control research as supported in the CDC Injury Research Agenda.

Acute Injury Care Research

Each year, Americans make between 30 and 40 million emergency department (ED) visits for injuries. While most injured patients are treated and released, many are admitted to inpatient trauma units and later receive rehabilitative services. The most favorable outcomes are achieved when acute care and subsequent rehabilitation are offered as early as possible and focus on returning patients to baseline or to an optimal level of functioning. Trauma systems are designed to match trauma patients with the acute care and rehabilitative facilities they need, but in many parts of the U.S. trauma systems are not fully operational or are nonexistent. Where these systems are lacking, as many as 30 percent to 40 percent of deaths among trauma patients are due to preventable problems in clinical care, including missed diagnoses and treatment delays.

Injuries are a major cause of disabilities in the U.S. Central nervous system injuries (those to the brain and spinal cord) are most likely to result in serious long-term disability. Each year, an estimated 80,000 Americans sustain a traumatic brain injury (TBI) that results in disability; an estimated 5.3 million Americans live with TBI-related disability. Although physical impairments from the injury may contribute to TBI disability, cognitive deficits are the hallmark, frequently resulting in secondary conditions such as depression and other adverse outcomes such as the inability to work. An estimated 177,000 to 200,000 people in the U.S. live with spinal cord injuries (SCI), and this number increases annually by as many as 20,000 individuals.

Research Objectives

Applicants are encouraged to propose studies that can feasibly be completed within the available funds and funding period. Proposed research for this program announcement must address one of the following research priorities. Applications that fail to address one of these topics will be deemed nonresponsive.

Unintentional Injury

1. Develop a theory-based intervention for use of supervision of children to reduce unintentional injury outcomes.

2. Evaluate existing and develop new methods to obtain exposure and injury

incidence data for sports, exercise and recreation-related injuries.

3. Identify risk and protective factors related to injury from childhood falls, crashes involving young drivers or related to motor vehicle and pedestrian travel of older adults.

4. Evaluate the effectiveness of environmental, behavioral, legislative or regulatory interventions to prevent pedestrian injuries or injuries related to sports, exercise, and recreation (including drowning).

5. Assess how tailoring, training, packaging, feasibility (and other dimensions of an effective intervention or policy) would promote greater adoption, usability and uptake, especially for interventions that impact older adult falls injury, transportation safety, and sports & recreation injury prevention (including drowning).

6. Evaluate theory-based strategies to increase dissemination of effective interventions that reduce injuries related to transportation, at home, or during recreation.

For more information on the unintentional injury research objectives, see Attachment 2 of this announcement. The attachment is posted along with this announcement on the CDC Web site: *http://www.cdc.gov/ncipc/ncipchm.htm*.

Violence Related Injury

1. Conduct studies to build knowledge on methods, structures, and processes to implement evidence-based interventions, programs and policies to prevent intimate partner violence, child maltreatment and youth violence. This research is intended to bridge the gap between prevention research and everyday practice by building a knowledge base about how evidence-based violence prevention information and strategies are disseminated, translated and integrated for use by communities and policymakers.

2. Evaluate the efficacy, effectiveness, and cost effectiveness of primary prevention interventions, programs, and policies to prevent perpetration of intimate partner violence, sexual violence, child maltreatment (includes physical, sexual, emotional abuse and neglect), youth violence or suicidal behavior. There is particular interest in assessing the impact of interventions, programs, or policies that may affect multiple forms of violence simultaneously.

3. Identify protective factors across at least two levels of influence (*e.g.*, individual, family, peers, school/workplace, neighborhood, community) that reduce risk for the perpetration of intimate partner violence, sexual violence, child maltreatment, youth violence or suicidal behavior among populations at elevated risk for engaging in such behaviors.

Injury Biomechanics

1. Use biomechanics research and the knowledge of injury tolerance and injury mechanisms to develop and/or evaluate interventions that address the following specific injury prevention and control problems. An intervention can be broadly defined as a specific action, policy, device or strategy designed to address injury prevention and control:

a. Falls that occur among older, community dwelling adults (*e.g.,* hip pads).

b. Injuries in mass trauma events.

c. Severe and disabling falls among children.

d. Sports, recreation, and exercise-related injuries (*e.g.,* playground and other play environments, safety gear).

e. Injuries associated with people initiating or increasing physical activity (*e.g.,* training programs or protective devices).

f. Injuries related to outdoor recreation (*e.g.,* vehicle design).

g. Motorcycling, bicycling and pedestrian injuries (*e.g.,* improved helmets or environments).

h. Injuries to child occupants of motor vehicles (*e.g.,* universal fasteners and alternative restraint designs).

i. Injuries to older drivers.

j. Injuries associated with the effects of emerging vehicle technologies.

2. Identify the biomechanics and specific injuries that would be highly predictive of diagnoses of intimate partner violence and child maltreatment, and improve case definitions.

3. Advance the biomechanical understanding of traumatic injury (*e.g.,* injuries to the brain, spinal cord, thorax/abdomen, extremities and joints) in children and older adults (greater than 65 years old) including: development of biofidelic models to elucidate injury physiology as well as pharmacologic, surgical, rehabilitation, and other interventions; improvement of injury assessment technology; impact injury mechanisms research; and quantification of injury-related biomechanical responses for critical areas of the human body (*e.g.,* brain and vertebral injury with spinal cord involvement).

4. Define the human tolerance limits for injury in children and older adults (greater than 65 years old), especially determining the differences in human tolerance by age, fitness level, and gender and the biomechanics and injury tolerances of tissue, bone, and other human structures as a prerequisite for developing interventions.

5. Identify the modifiable risk factors for and mechanisms of nonfatal whiplash injuries of the neck and back.

Acute Injury Care

1. Develop and evaluate protocols that provide onsite interventions in acute care settings or linkages to off-site services for patients at risk of injury or psychosocial problems following injury.

2. Identify methods and strategies to ensure that people with traumatic brain injuries (TBI) and spinal cord injuries (SCI) receive needed services.

3. Identify the effects on acute injury care of inter-jurisdictional, legal, governmental, and interdisciplinary issues related to mass casualty events.

4. Identify and evaluate the components of trauma systems which contribute to improvement in care of the injured.

5. Develop and evaluate new methods for linking prehospital databases to trauma registries, and other hospital databases, including those related to subsequent levels of care (*e.g.,* rehabilitation).

Approximately $500,000 of the total award amount will be reserved to fund up to five proposals that address acute injury care research.

Rigorous evaluations are needed to determine the effectiveness of interventions, programs, and policies addressing the prevention of injury. 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.

For randomized trials, applicants are encouraged to clearly state how study subjects, whether individuals or groups, were selected, randomized, and followed through the trial. One relevant useful guidance document is Moher D, Schulz KF, Altman D, The CONSORT Statement, JAMA 2001;285:1987–2001.

II. Award Information

Type of Award: Grant.

Mechanism of Support: R49.

Fiscal Year Funds: 2005.

Approximate Total Funding: $900,000. (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: Nine (Up to five of these awards will be made in the area of acute care research).

Approximate Average Award: $100,000. (This amount includes both direct and indirect costs.)

Floor of Award Range: None.

Ceiling of Award Range: $100,000. (This amount includes both direct and indirect costs.)

Anticipated Award Date: August 30, 2005.

Budget Period Length: 12 months.

Project Period Length: One year.

Allowable costs include partial salary and tuition support for the applicant; direct research project expenses, such as trainee stipends, interviewer costs, data processing, participant incentives, statistical consultation services, and supplies; and travel to one scientific meeting, if adequately justified. Applicants should also include travel costs for one, two-day trip to CDC in Atlanta to present research findings.

III. Eligibility Information

III.1. Eligible Applicants

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

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

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

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, 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.

Eligible applicants may enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application.

It is especially important that the abstract of your grant application (Description, PHS 398 form page 2) reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

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.
- Grant applications must demonstrate an overall match between the applicant's proposed theme and research objectives and the program priorities as described under the heading, ''Research Objectives.''
- Applications must demonstrate effective and well-defined working relationships within the performing organization and with outside entities, which will ensure implementation of the proposed activities.
- *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

- The principal investigator must have a research or a health-professional doctorate-level degree from an accredited program and have demonstrated the capacity or potential for highly productive research in the period after the doctorate, commensurate with level of experience.
- Applicants who have been the principal investigator on an RO1 or RO1-equivalent health-related research grant or who have had equivalent injury-related research support from an existing Injury Control Research Center (ICRC) are not eligible. Recipients of dissertation research grants or NIH Small Grant Awards are eligible to apply.
- A principal investigator who has specific authority and responsibility to carry out the proposed project.
- The ability of the principal investigator to carry out injury control research projects as defined under Attachment 1 of this program announcement. The attachment is posted along with this announcement on the CDC Web site: *http://www.cdc.gov/ncipc/ncipchm.htm.*

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

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:* Two.
- *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 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.
- Brief description of the scope and intent of the proposed research work.

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

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. Your DUNS number must be entered on line 11 of the 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. Follow the PHS–398 instructions for non-modular budget research grant applications.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application, which are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS–398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

In addition to the instructions provided in the PHS 398 for writing the Description on page 2 of the PHS 398 form, structure the Description using the following components:

- Statement of the problem.
- Purpose of the proposed research.
- Methods, including study population, data sources and any statistical analyses to be performed.
- Implications for prevention.

The Description (abstract) should answer the following questions:

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

You must include a research plan in your application. The research plan should be no more than 25 pages, printed on one side, single spaced, with one half-inch margins, and unreduced 12-point font. The research plan should address activities to be conducted over the entire project period. Use the information in the Research Objectives, Administrative and National Policy Requirements, and Application Review Information sections to develop the application content. The research plan should include the following information:

- The project's focus, a justification for the research proposed, and a description of the scientific basis for the research. The focus should be based on recommendations in ''Healthy People 2010'' (*http://www.healthypeople.gov*) and the ''CDC Injury Research Agenda,'' (*http://www.cdc.gov/ncipc/pub-res/research_agenda/agenda.htm*) and should seek creative approaches that will contribute to a national program for injury control.
- Specific, measurable, and time-framed objectives.
- A detailed plan describing the methods, which will achieve the objectives, including their sequence. A comprehensive evaluation plan is an essential component of the application.
- A description of the roles and responsibilities of the principal investigator and the mentor.
- A description of those activities related to, but not supported by, the grant.
- A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.
- An explanation of how the research findings will contribute to the national effort to reduce the morbidity, mortality and disability caused by injuries within three to five years from project start-up.

Additional materials required: In addition to the completed PHS 398 application form, the applicant must also submit the following materials, attached to the application as appendices:

- An official transcript of the applicant's graduate school record.
- A statement describing the applicant's prior research training and experience and short and long term career goals in injury research, including a paragraph describing why he or she qualifies as a new investigator.
- A letter from a senior injury researcher acknowledging that he or she has read the application and agrees to serve as a mentor. The letter should also include: (1) An outline of the mentor's specific roles and responsibilities and time commitment (percent time); (2) a proposed plan for providing scientific advice and consultation to the applicant; and (3) a two-page biography of the mentor. (Use the Biographical Sketch page in application form PHS 398.)
- A justification for any proposed tuition support.

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

For additional help in preparing your grant application please see the ''frequently asked questions'' section on the NCIPC Web page at: *http://www.cdc.gov/ncipc/res-opps/2004pas.htm*.

IV.3. Submission Dates and Times

LOI Deadline Date: December 6, 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 2, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office (PGO) (not NIH) by 4 p.m. eastern time on the deadline date. If you submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on LOI and grant application content, 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 you did not meet the submission requirements.

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

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

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

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board (IRB) approvals are in place.
- Grant funds will not be made available to support the provision of direct care.
- Eligible applicants may enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application.
- Allowable costs include partial salary and tuition support for the applicant; direct research project expenses, such as trainee stipends, interviewer costs, data processing, participant incentives, statistical consultation services, and supplies; and travel to one scientific meeting, if adequately justified.
- Applicants should also include travel costs for one, two-day trip to CDC in Atlanta to present research findings.
- Funds for tuition support are limited to no more than 20 percent of the overall award and their use must be generally related to the content and methods of the proposed research.
- Indirect costs for this trainee-related grant are limited to eight percent.

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: NCIPC Extramural Resources Team, Centers for Disease Control and Prevention, 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—CE05–021, 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: NCIPC Extramural Resources Team, CDC, National Center for Injury Prevention and Control.

Address for Express Mail or Delivery Service: 2945 Flowers Road, Yale Building, Room 2054, Atlanta, Georgia 30341.

Address for U.S. Postal Service Mail: 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 grant. 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 improve the control and prevention of disease and injury and to enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

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

The review criteria are as follows:

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

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

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)? Is there a

prior history of conducting injury-related research?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

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

Dissemination: What plans have been articulated for disseminating findings?

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

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

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

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

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

V.2. Review and Selection Process

Applications will be reviewed for completeness by the PGO and for responsiveness by NCIPC. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

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

- 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.

The primary review will be a peer review conducted by NCIPC Initial Review Group (IRG). Applications may be subjected to a preliminary evaluation (streamline review) by the IRG to determine if the application is of sufficient technical and scientific merit to warrant further review. NCIPC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by the IRG. These applications will be reviewed for scientific merit using current NIH criteria (a scoring system of 100–500 points) to evaluate the methods and scientific quality of the application.

The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of the 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 ACIPC 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:

- 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 ''CDC Injury Research Agenda.'' (*See* Attachment 1, Resource Materials.) The attachment is posted along with this announcement on the CDC Web site: *http://www.cdc.gov/ncipc/ncipchm.htm*).
- Budgetary considerations.

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 ACIPC, consultation with NCIPC senior staff, and the availability 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.

V.3. Anticipated Announcement and Award Dates

August 30, 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–3 Animal Subjects 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–21 Small, Minority, and Women-Owned Business.
• AR–22 Research Integrity.

Additional information on AR–1 through AR–22 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, 2003 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 toward 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: 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. Financial status report, no more than 90 days after the end of the budget period.

2. The final performance report, no more than 90 days after the end of the project period. The final performance report will be a brief summary (2,500 to 4,000 words in length) written in non-scientific [laymen's] terms. The report should highlight the findings and their implications for injury prevention programs, policies, environmental changes, etc. The grant recipient will also include a description of the dissemination plan for research findings. This plan will include publications in peer-reviewed journals and ways in which research findings will be made available to stakeholders outside of academia (*e.g.*, State injury prevention program staff, community groups, public health injury prevention practitioners, and others). CDC will place the summary report and each grant recipient's final report with the National Technical Information Service (NTIS) to further the agency's efforts to make the information more available and accessible to the public.

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: Paul Smutz, Ph.D, Project Officer, 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) 488–1508, E-mail: *wsmutz1@cdc.gov*.

For questions about peer review, contact: Gwendolyn Cattledge, Ph.D, Scientific Review Administrator, 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: Pamela Render, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2712, E-mail: *PLR3@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.''

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 Disease Control and Prevention

Grants for Traumatic Injury Biomechanics Research

Announcement Type: New.

Funding Opportunity Number: CE05–023.

Catalog of Federal Domestic Assistance Number: 93.136.