

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Dissemination Research on Fall Prevention: Development and Testing of an Exercise Program Package To Prevent Older Adult Falls

Announcement Type: New.

Funding Opportunity Number: CEO5-029.

Catalogue of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: December 8, 2004.

Application Deadline: February 7, 2005.

Executive Summary: This research study is a Cooperative Agreement that seeks to: (a) Translate an effective exercise fall intervention for older adults into a program package that can be delivered to community-based organizations for implementation with older adults, and (b) develop and implement dissemination research that is focused on reach and uptake (adoption), feasibility for the organizations offering the program and the individual participants, fidelity by the provider to the key elements that made the original intervention effective, and acceptability of the program to the organizations and to the older adult recipients.

Development of the program package will involve developing multiple package components, including the materials needed to: (a) Recruit organizations and individuals, (b) train program providers, and (c) deliver and implement the program in a non-research setting.

The Principal Investigator (PI) is expected to seek collaboration with and feedback from relevant experts such as representatives from the administrations of senior service organizations; technical experts in areas such as health care, physical therapy, and occupational therapy; health education specialists; and community-dwelling seniors. In addition, the PI may utilize video and other media experts.

As a result of this translation and dissemination research, future dissemination activities will be informed about strategies that may enhance reach; increase organizational uptake in diverse, non-research, community-based settings; improve provider fidelity to key elements in program delivery; and increase organizations' and older adults' acceptance of the fall prevention exercise program.

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.

Background: The problem of fall-related injuries among persons aged 65 and older is enormous—accounting for 11,623 deaths¹ and over 1.6 million non-fatal emergency department-treated injuries¹ each year. With a rapidly increasing older adult population, it is essential to address the problem of older adult falls. While physical activity provides many health benefits, certain types of exercise specifically address known fall risk factors by improving balance and lower body strength. The 2003 CMS-sponsored Rand Report on this topic showed that exercise interventions can reduce the rate of falls by 19 percent (pooled risk ratio: 0.81, [95 percent CI 0.72, 0.92])². While a number of exercise interventions have demonstrated effectiveness in a research setting, no researcher has taken the next steps: Translating the intervention into a program that retains the key elements that made the original research effective, implementing the program in a community setting, and conducting research to test dissemination factors such as uptake and acceptability of the program in a community-based setting.

References:

1. Centers for Disease Control and Prevention (CDC). Web-based Injury Statistics Query and Reporting System (WISQARS) [Online]. (2004). National Center for Injury Prevention and Control (NCIPC) and, CDC (producer). Available from: URL: www.cdc.gov/ncipc/wisqars. [Cited 26 July 2004].

2. Healthy Aging Initiative Evidence Reports. Falls Prevention Interventions in the Medicare Population. Rand Corporation, Contract Number 500-98-0281. Available from: URL: www.cms.hhs.gov/healthyaging/fallspi.asp

Purpose: The purpose of the programs is to support research on translating an exercise intervention that rigorous research has shown is effective in reducing falls among older adults into a program; testing implementation of the program in a community setting; and conducting dissemination research focusing on reach, uptake (adoption), feasibility, fidelity of the implementation, and acceptability.

This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention. Specifically, it addresses Objective 15-27, to reduce deaths from falls, and Objective 15-28, to reduce hip fractures among people age 65 and older.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for (NCIPC):

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

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

Outcomes also should be in alignment with the NCIPC Research Agenda priority areas to disseminate effective interventions to reduce injuries at home and in the community and to reduce older adult falls and fall-related injuries. Specifically, "Evaluate strategies for widespread dissemination and implementation of effective interventions to reduce injuries at home and in the community." (NCIPC Research Agenda, p19); "Research has demonstrated that many interventions at home and in the community work.

* * * Encouraging widespread adoption of these efficacious interventions calls for dissemination research. * * * Demonstration programs should be developed and evaluated to determine the effectiveness of various persuasive communications techniques, audience segmentation, tailored messaging, and collaboration models to speed diffusion and widen adoption." (NCIPC Research Agenda, p19)

"[Pertaining to older adult falls:] Research is needed to develop and evaluate approaches to implementing and disseminating effective fall prevention programs in the community. * * * This includes research to identify the best formats and channels for delivering interventions to ensure that older adults adopt them." (NCIPC Research Agenda, p22)

Available from: URL: www.cdc.gov/ncipc/pub-res/research_agenda/agenda.htm.

Outcome measures of interest will include:

1. Reach and uptake (adoption) at organizational and individual levels;
2. Fidelity to the key elements when the program is implemented;
3. Feasibility at organizational and individual levels; and
4. Acceptability at the organizational and individual levels.

Research Objectives:

Note: Applicants will be expected to identify an effective exercise intervention to reduce older adult falls. Examples of such interventions may be found in:

Healthy Aging Initiative Evidence Reports. Falls Prevention Interventions in the

Medicare Population. Rand Corporation, Contract Number 500–98–0281. Available from: URL: www.cms.hhs.gov/healthyaging/fallspi.asp

Gillespie LD, Gillespie WJ, Robertson MC et al. Interventions for preventing falls in elderly people (Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chinchester, UK: John Wiley & Sons, Ltd.

This Announcement does not include dissemination of exercise programs to nursing home residents or frail, home-bound older adults where medical screening and follow up, or medical monitoring, is required.

Specific interventions that fit the requirements of this Announcement and have credible evidence of effectiveness based on rigorous research trials include:

(a) Tai Chi tailored for community-dwelling older adults offered as group classes.

(b) Tai Chi group classes plus related activities undertaken by individuals in their homes.

(c) Community-based group exercise classes focusing on strength, balance, and endurance training.

(d) Community-based group exercise classes focusing on strength, balance, and endurance training, including individualized programs.

1. To translate an effective exercise fall intervention for older adults into a program that can be implemented in community settings.

Additional objectives are to translate the intervention into a program; create a program package of materials; recruit organizations for testing; implement the program in a community setting; evaluate the results of the implementation with particular emphasis on dissemination research questions of reach, uptake (adoption), feasibility, and implementation fidelity and acceptability; refine the fall prevention program, recruit a second organization and implement the revised program; and produce a final package that can be broadly disseminated and used nationwide. (**Note:** broad dissemination and nationwide use is not a part of this Announcement).

2. To identify the key elements that made the intervention effective. In the absence of a component analysis which is rare in behavioral studies, the original investigators will need to derive these key elements based on their publications, notes, recall, and judgment. They will likely need to consult with their former research project staff and others, consider the underlying theoretical models used in their intervention design, and examine the data that was obtained in their study. Applicants other than the

original investigators will need to demonstrate the ability to carry out these processes.

3. To conduct research on translating and disseminating effective exercise fall interventions into programs that can be implemented in community settings.

Research questions to be addressed might include:

(a) Reach—Who are you most interested in reaching and how many persons from this target audience will be reached?

(b) Uptake (adoption)—Do organizations and individuals who learn of the program consider using it, actually use it, and use it fully? What barriers and facilitators to use can be identified?

(c) Feasibility—How much time, money, staff, space and other resources are needed vs. what is available?

(d) Fidelity—Are the key components that made the intervention effective maintained when the program is implemented?

(e) Acceptability—How acceptable is the intervention to those it will impact; e.g., are cultural norms taken into account? Is the program acceptable at organizational and individual levels?

(f) Adaptability—Can the intervention vary, as needed depending on the audience?

Translational research has been utilized to develop programs in topic areas such as HIV/AIDS. Two examples of this type of research are:

1. Kraft JM. Mezzoff JS. Sogolow ED. Neumann MS. Thomas PA. A technology transfer model for effective HIV/AIDS interventions: science and practice. *AIDS Education & Prevention*. 12(5 Suppl):7–20, 2000.

2. Sogolow ED. Kay LS. Doll LS. Neumann MS. Mezzoff JS. Eke AN. Semaan S. Anderson JR. Strengthening HIV prevention: application of a research-to-practice framework. *AIDS Education & Prevention*. 12(5 Suppl):21–32, 2000.

Additional examples of translation and dissemination research are ongoing at the National Cancer Institute, National Institute of Mental Health, and National Institute on Drug Abuse, among others. Examples may be found at URLs:

www.nci.nih.gov/search/results.aspx
www.nimh.nih.gov/dsir/dirp.cfm
www.nimh.nih.gov/scientificmeetings/chddimtg.cfm
www.drugabuse.gov/CTN/whatisblending.html

Although not specific to fall prevention, effective evidence-based exercise interventions have been identified and these may help inform the research translation process. These interventions have been described in:

1. Task Force on Community Preventive Services. Recommendations to increase physical activity in communities. *American Journal of Preventive Medicine*, 2002; 22: 67–72.

2. Kahn, EB, Ramsey, LT, Brownson, RC, et al. The effectiveness of interventions to increase physical activity: a systematic review. *American Journal of Preventive Medicine*, 2002, 22:73–107.

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

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

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

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

Activities:

Awardee activities for this program are as follows:

For the selected effective exercise intervention, a series of activities will take place over the three years of the Cooperative Agreement:

Year One: Planning and Development

- Identify those key elements that made this intervention effective.
- Establish an ad hoc expert group to guide and support development of a draft fall prevention program package.
- Develop a curriculum (including a variety of educational materials such as audio, video, and print) that translates these key elements into a community-based exercise program.;
- Develop materials for recruitment of organizations and individuals.;
- Develop materials for training providers of the exercise program, including criteria-based performance standards.
- Create the draft program package of materials;
- Develop a research protocol and submit for Institutional Review Board (IRB) review by all cooperating institutions participating in the research study.;
- Develop and pilot test evaluation instruments to assess reach, uptake (adoption), feasibility, fidelity, and acceptability.

- Recruit (two to three) community-based organizations for implementation. This applies only where organizational settings are relevant such as where the program takes place in a senior center.

- Revise materials pertaining to recruitment of organizations.

Year Two: Implementation

- Recruit older adults into the program.;
- Train personnel.;
- Implement the program in one community setting. Provide the program to a small number of older adults (less than eight), for a predetermined period depending on the program design (e.g., two to three months).

- Make minor revisions to the provider materials as needed and repeat implementation in same setting two to three times.

- Revise all materials.
- Recruit older adults into the program in a new setting, train personnel, and implement the program following guidance above.

- In all instances, employ the evaluation tools to collect data required to address the research questions previously listed under "Research Objectives."

Year Three: Evaluation

- Evaluate the dissemination using data collected during Year Two; analyze reach, uptake (adoption), feasibility, implementation fidelity, and acceptability;

- Use findings to revise and refine the program package.

- Incorporate dissemination research results to produce a final program package that will enable the program to be broadly disseminated in various community settings nationwide.

- Prepare a paper for publication in a peer review practice journal.

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

CDC Activities for this program are as follows:

1. Provide up-to-date scientific information, technical assistance, and guidance in the design and conduct of the research when and where needed or requested.

2. Provide to awardees:

- (a) Scientific information and guidance in translation and dissemination research design, data collection methods, and data quality assurance when requested;

- (b) If necessary, technical assistance in developing data collection instruments and methods for data management;

- (c) If necessary, guidance in developing a research protocol for annual Institutional Review Board (IRB) review for use by all cooperating institutions participating in the research study; and

- (d) Technical assistance and guidance in analysis and dissemination of results including the preparation of manuscripts when required.

3. The CDC IRB will review the protocol initially and on at least an annual basis until the research study, including analyses, is completed and will assist in ensuring human subjects assurances are in place as needed.

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

5. Convene meetings of recipients for the exchange of information.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed under "CDC Activities" above.

Mechanism of Support: U49.

Fiscal Year Funds: 2005.

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

Approximate Number of Awards: One.

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

Floor of Award Range: None.

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

Anticipated Award Date: September 1, 2005.

Budget Period Length: 12 months.

Project Period Length: Three years.

Throughout the project period, CDC's commitment to continuing the awards will be dependent 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:

- Research institutions.
- Universities.
- Colleges.
- Public nonprofit organizations.
- Private nonprofit organizations.
- For profit organizations.
- Small, minority, women-owned businesses.
- 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 Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

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.

Special Requirements:

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

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

- In order to plan the application review more effectively and efficiently, CDC requires that you submit a Letter of Intent (LOI) to apply for this program. See "IV.3. Submission Dates and Times" for more information on deadlines.

- Application must demonstrate credible evidence of the effectiveness in a research study of any proposed intervention or that no negative effects have been demonstrated because of the intervention.

- Application must include an exercise program that has been subject to rigorous research. Rigorous research does not include studies that focus exclusively or primarily on participant satisfaction rather than falls as the primary outcome.

- Participants must be independent, community dwelling older adults (for example, the applicant should not propose to disseminate via health care providers to older adults who reside in assisted living or nursing homes).

- The applicant must provide evidence such as publications from peer reviewed journals (in the appendix of the application) that demonstrate expertise in:

- (a) Designing and conducting original intervention research on exercise for fall prevention; and/or

- (b) Conducting translation/dissemination research.

- If the applicant is not strong in both areas, the applicant must demonstrate enhanced capacity to perform the translation and dissemination research by including documentation of potential consultants or collaborators who have the relevant other area of expertise.

- The applicant must provide documentation of collaborating experts (e.g., administrators of senior centers, technical experts, and community-based seniors) describing the areas of expertise and indicating willingness to collaborate and areas of potential collaboration.

- **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: 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.

PIs must demonstrate that they have the authority to carry out this research. For example, if a PI is affiliated with a university, he or she must be a faculty member and not a visiting scientist.

PIs are encouraged to submit only one proposal in response to this program

announcement. With few exceptions (e.g., research issues needing immediate public health attention), only one application per 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: 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: 25 pages.
- Font size: 12-point un-reduced.
- Double-spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon.

• Your LOI must contain the following information:

Descriptive title of the proposed research

- Name, address, E-mail address, telephone number, and FAX number of the Principal Investigator.

- Names of other key personnel.

- Participating institutions.

- Number and title of this Announcement.

Application: Follow the PHS 398 application instructions for content and formatting of your application. If the instructions in this announcement differ in any way from the PHS 398 instructions, follow the instructions in this announcement. For further assistance with the PHS 398 application form, contact PGO-TIM staff at 770-488-2700, or contact GrantsInfo,

Telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

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

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access 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/pubcomm.htm>.

This announcement uses the non-modular budgeting format.

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

The Description (abstract) should answer the following questions:

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

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

Additional documentation that may be required for submission with your application is listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

Letter of Intent (LOI): December 8, 2004.

CDC requires that you submit a LOI if you intend to apply for this program. Although the LOI will not be evaluated, and does not enter into review of your

subsequent application, failure to submit a timely LOI will preclude you from submitting an application.

Application deadline date: February 7, 2005.

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

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

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

IV.4. Intergovernmental Review of Applications

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

IV.5. Funding Restrictions

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

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board approvals are in place. Sufficient time and resources should be devoted to preparing an acceptable IRB Protocol package. Funds for human subjects recruitment and human subjects research will be withheld until appropriate IRB approval has been obtained.

- Reimbursement of pre-award costs is not allowed.

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

IV.6. Other Submission Requirements

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

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

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

Telephone: 770-488-4037.

Fax: 770-488-1662.

Email: 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 #CE05-029, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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

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

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

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

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

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

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

The review criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Will study advance scientific knowledge of how to disseminate community-based interventions for preventing older adult fall-related injuries.

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? To what extent do the applicant's work plan and timetable include development of program package materials, specification of relevant experts and agreements with them, recruitment of organizations, staffing including trainer, training for providers, program delivery; and dissemination research design and implementation.

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)? Does the PI have the authority to conduct the project?

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

To what extent have the applicant and proposed collaborators documented:

a. Their history and current capacity to provide a leadership function in conducting translation/dissemination research of an exercise program package to reduce falls among older adults.

b. A willingness to partner with CDC so that the Applicant Activities and CDC Activities are undertaken in a collaborative fashion as intended for Cooperative Agreement recipients. This would include a willingness to attend and participate in technical assistance and planning meetings and related travel to Atlanta coordinated by the CDC for all Cooperative Agreement recipients.

c. Their organizational capacity to realize the objectives of the Cooperative Agreement.

d. Their management operation, structure and/or organization. An organizational chart of the applicant's organization should be included as an appendix. Additionally, the applicant should include within their management plan the specific role and mechanisms to be established to ensure effective coordination, communication and shared decision making among the involved agencies/organizations.

e. A staffing plan for the project, noting existing staff as well as additional staffing needs. The responsibilities of individual staff members including the level of effort and allocation of time for each project activity by staff position should be included. If relevant, the specific staff positions within other involved state level agencies, both in-kind and funded, should be described.

f. CVs for the PI and co-PIs (if any), and CVs, resumes, and/or biosketches for current, proposed, and in-kind staff,

and position descriptions for all proposed positions to be funded under this cooperative agreement) should be included as an appendix. This should include the use of consultants, as 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.

Applicants should consider the possible need for IRB and/or OMB submissions early in the Cooperative Agreement and plan appropriately for their completion to avoid delays and restriction of funds.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

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

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

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

V.2. Review and Selection Process

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

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

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

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

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the primary review committee SEP, recommendations by the external secondary review committee of the Science and Program Review Subcommittee of the Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

The primary review will be a peer review conducted by the SEP. A committee of reviewers with appropriate expertise will review all

applications for scientific merit using current National Institutes of Health (NIH) criteria (a scoring system of 100–500 points) to evaluate the methods and scientific quality of the application. All categories are of equal importance, however, the application does not need to be strong in all categories to be judged likely to have a major scientific impact.

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

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

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 NCIPC Injury "Research Agenda."

d. Budgetary considerations including the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

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

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

V.3. Anticipated Announcement of Award Date

September 1, 2005

VI. Award Administration Information

VI.1. Award Notices

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

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

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

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

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements.
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR-6 Patient Care.
- AR-7 Executive Order 12372.
- AR-9 Paperwork Reduction Act Requirements.

- AR-10 Smoke-Free Workplace Requirements.

- AR-12 Lobbying Restrictions.

- AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities.

- AR-14 Accounting System Requirements.

- AR-22 Research Integrity.

- AR-23 States and Faith-Based Organizations.

- AR-24 Health Insurance Portability and Accountability Act Requirements (HIPAA).

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

- AR-25 Release and Sharing of Data

Starting with the December 1, 2004 receipt date, all "Requests for Applications (RFA)/Program Announcements (PA)" soliciting proposals for individual research projects of \$500,000 or more in total (direct and indirect) costs per year require the applicant to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing and release, including information on the timeliness of the data and the name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing and release may also be appropriate in other sections of the application (*e.g.* background and significance, or human subjects requirements). The content of the data sharing and release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing and release plan will not count towards the application page limit and will not factor into the determining scientific merit or the priority scoring. Investigators should seek guidance from their institutions on issues related to institutional policies, and local IRB rules, as well as local, state and federal laws and regulations, including the Privacy Rule.

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or by visiting the NCIPC internet Web site at:

http://www.cdc.gov/ncipc/osp/sharing_policy.htm

VI.3. Reporting

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

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

- a. Current budget period activities objectives.

- b. Current budget period financial progress.

- c. New budget period program proposed activity objectives.

- d. Budget.

- e. Measures of effectiveness.

- f. Additional requested information.

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

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

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

VII. Agency Contacts

We encourage inquiries concerning this announcement.

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

For scientific/research issues, contact: Karin Mack, Ph.D., National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy NE., Mailstop K-63, Atlanta, GA 30341. Telephone: 770-488-4389. E-mail: KMack@cdc.gov.

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

For financial, grants management, or budget assistance, contact: James Masone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. E-mail: JMasone@cdc.gov.

VIII. Other Information

This and other CDC funding opportunity announcements can be

found on the CDC web site, Internet address: 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.

[FR Doc. 04-24715 Filed 11-5-04; 8:45 am]

BILLING CODE 4163-18-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Injury Surveillance and Prevention Program

Announcement Type: New.

Funding Opportunity Number: CE05-027.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: December 8, 2004.

Application Deadline: February 7, 2005.

I. Funding Opportunity Description

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

Purpose: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2005 funds for a cooperative agreement program for the development, enhancement, and integration of injury prevention and control and surveillance programs. The purpose of this program is to enable State public health agencies to develop or strengthen their organizational focus related to the prevention and control of injuries and to develop or strengthen their injury surveillance programs, particularly those with a focus on traumatic brain injury (TBI). This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

This announcement incorporates funding guidance for the following four components: Part A—the Integrated Core Injury Prevention and Control (ICIPC) Program, Part B—the Traumatic Brain Injury Extended Surveillance (TBIES) Program, Part C—the Traumatic Brain Injury Emergency Department (TBIED) Surveillance Program and Part D—the Traumatic Brain Injury Service Linkage (TBISL) Program. All States/territories must qualify and be recommended for funding for Part A (ICIPC) in order to be eligible for Part B

(TBIES), Part C (TBIED) or Part D (TBISL). The ICIPC component supports the planning, implementation and integration of comprehensive injury prevention and control activities with basic injury surveillance activities. CDC defines injury program integration as a coordinated approach to reducing the incidence, morbidity and mortality of injury through surveillance and prevention efforts. The TBIES component supports efforts to provide expanded information on the incidence of traumatic brain injury. The TBIED component supports efforts to provide information on the incidence of mild traumatic brain injury treated in the emergency department. The TBISL component supports efforts to link individuals with traumatic brain injury to information about services.

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:

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

2. Monitor and detect fatal and non-fatal injuries.

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: <http://www.cdc.gov/od/ads/opspoll1.htm>

Activities

Part A: The Integrated Core Injury Prevention and Control (ICIPC) Program

In conducting activities to achieve the purpose of Part A of this program, the recipient will be responsible for incorporating the core components of a model State injury prevention program as outlined in the STIPDA: Safe States—2003 Edition. For a downloadable version of this document, please see the STIPDA Web site at the following Internet address: <http://www.stipda.org/safestates.htm>. Activities to be followed related to this requirement are described below. CDC has developed performance measures to evaluate recipients' progress in meeting ICIPC requirements. These performance measures are listed following each associated recipient activity. Activities are as follows:

- Building a Solid Infrastructure for Injury Prevention and Control.
 - Enhance comprehensive injury prevention and control infrastructure by acquiring key staff and associated resources to