

Dated: January 31, 2003.

**Thomas Bartenfeld,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30DAY-25-03]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and

Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

**Proposed Project:** Data Collection on Attention Deficit Hyperactivity Disorder (ADHD)—New—National Center for Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC). This project will collect data from proxy respondents on children ages 4 to 10 with and without ADHD. This program addresses the Healthy People 2010 focus area of Mental Health and Mental Disorders, and describes the prevalence,

treated prevalence, select co-morbid conditions, secondary conditions, and health risk behavior of ADHD.

#### Background

The purpose of this program is to support research in ADHD and the exploration of other health conditions and health risk behaviors to children with the disorder. The main objectives of the project are to determine the prevalence or treated prevalence of children with ADHD in a defined community; to identify rates of select co-morbid or secondary conditions in children with ADHD in a defined community; to identify types and rates of health risk behaviors in children with ADHD; and to describe current and previous receipt of treatment in children with ADHD. The estimated annualized burden is 4,367 hours.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
VADTRS/SDQ (Teacher Report) .....	1,350	1	6/60
Two-Question Previous Diagnosis and Treatment Screener (Parent) .....	22,000	1	1/60
Health Risk Behavior Survey (Parent Report) .....	2,500	1	10/60
Demographic Survey (Parent) .....	2,500	1	5/60

Dated: February 3, 2003.

**Thomas Bartenfeld,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03023]

#### Grants for Acute Care, Rehabilitation, and Disability Prevention Research; Notice of Availability of Funds

##### A. Authority and Catalog of Federal Domestic Assistance Number

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. The catalog of Federal Domestic Assistance number is 93.136.

##### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for grants for Acute Care,

Rehabilitation and Disability Prevention Research. This program addresses the "Healthy People 2010" focus areas of Injury and Violence Prevention.

The purposes of the program are to:

1. Solicit research applications that address the priorities reflected under the heading, "Program Requirements."

2. Build the scientific base for the prevention and control of injuries, disabilities and deaths.

3. Encourage professionals from a wide spectrum of disciplines of engineering, epidemiology, medicine, biostatistics, public health, law and criminal justice, behavioral and social sciences to perform research in order to prevent and control injuries more effectively.

4. Encourage investigators to propose research that involves intervention development and testing as well as research on methods; to encourage individuals, organizations, or communities to adopt and maintain effective intervention strategies.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC): Develop new or improved approaches for preventing and controlling death and disability due to injuries.

##### C. Eligible Applicants

Applications may be submitted by public and private nonprofit and for profit organizations and by governments and their agencies; that is, universities, colleges, technical schools, research institutions, hospitals, other public and private nonprofit and for profit organizations, community-based organizations, faith-based organizations, state and local governments or their bona fide agents, including 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, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and/or women-owned businesses.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration.

The following are applicant requirements:

1. A principal investigator who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury control research in peer-reviewed journals.

3. Effective and well defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.

4. The ability to carry out injury control research projects as defined under Attachment 2 (1.a–c). The attachment is posted with this program announcement on the CDC Web site: <http://www.cdc.gov/ncipc/ncipchm.htm>.

5. The overall match between the applicant's proposed theme and research objectives and the program priorities as described under the heading, "Program Requirements."

#### **D. Funding**

##### *Availability of Funds*

Approximately \$1,800,000 is available in FY 2003 to fund approximately 6–9 awards. It is expected that the awards will begin on or about September 1, 2003, and will be made for a 12-month budget period within a project period of up to three years. The maximum funding level for each project will not exceed \$300,000 per year (including both direct and indirect costs) or \$900,000 for a three year project period.

Applications that exceed the funding caps noted above will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Consideration will also be given to current grantees who submit a competitive supplement requesting one year of funding to enhance or expand existing projects, or to conduct one-year pilot studies. These awards will not exceed \$150,000, including both direct and indirect costs. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant and are based on the availability of funds.

Continuation awards within the approved project period will be made based on satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops (travel expenses for this annual one day meeting should be included in the

applicant's proposed budget), the achievement of work plan milestones reflected in the continuation application, and the availability of funds.

##### *Funding Priority*

The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Requirements."

##### *Use of Funds*

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.

##### *Recipient Financial Participation*

Matching funds are not required for this program.

#### **E. Program Requirements**

In conducting activities to achieve the purpose of this program, the recipient will be responsible for accomplishing one of the following activities:

*Research Activity 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 psycho social problems following injury.

*Research Activity 2:* Develop and apply methods that can be used to calculate population-based estimates of the incidence, costs, and long-term consequences of spinal cord injury (SCI) and non-hospitalized traumatic brain injury (TBI).

*Research Activity 3:* Identify methods and strategies to ensure that people with TBI and SCI receive needed services.

For more information on all 3 Research Activities, see Attachment 3 of this announcement as posted on the CDC Web site.

#### **F. Content**

##### *Letter of Intent (LOI)*

A LOI is optional for this program. The narrative should be no more than two double-spaced pages, printed on one side, with one inch margins, and unredacted 12-point font. The letter should identify the announcement number, the name of the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

##### *Applications*

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 pages, printed on one side, with one-inch margins, and unredacted 12-point font.

Applications should follow the PHS–398 (Rev. 5/2001) application and Errata Sheet (see Attachment 4 of this announcement as it is posted on the CDC Web site). The narrative should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce injury morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in "Healthy People 2010" and the "CDC Injury Research Agenda," and should seek creative approaches that will contribute to a national program for injury control.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

4. A description of the principal investigator's role and responsibilities.

5. A description of all the project staff, regardless of their funding source. It should include their titles, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by, the grant.

7. 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.

8. A detailed first year's budget for the grant, including future annual projections, if relevant.

9. 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.

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 two 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.

## F. Submission and Deadline

### *Letter of Intent (LOI) Submission*

On or before March 7, 2003, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### *Application Forms*

Submit the signed original and two copies of the PHS 398 (OMB Number 0925-0001)(adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>. 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) at: 770-488-2700. Application forms can be mailed to you.

### *Submission Date, Time, and Address*

The application must be received by 4 p.m. Eastern Time April 8, 2003. Submit the application to: Technical Information Management—PA03023, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146. Applications may not be submitted electronically.

### *CDC Acknowledgment of Application Receipt*

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

### *Deadline*

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

## H. Evaluation Criteria

### *Application*

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the "Eligible Applicants" Section (Items 1-5). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation (streamline review) by a peer review committee, the Injury Research Grant Review Committee (IRGRC), to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRGRC. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

Competing supplemental grant awards may be made, when funds are available, to support research work or activities not previously approved by the IRGRC. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the secondary review group.

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

1. The primary review will be a peer review conducted by the IRGRC. All applications will be reviewed 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. Factors to be considered will include:

a. 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?

b. 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?

c. Innovation—Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

d. Investigator—Is the principal investigator appropriately trained and well-suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other significant investigator participants? Is there a prior history of conducting injury-related research?

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

f. Ethical Issues—What provisions have been made for the protection of human subjects and the safety of the research environments? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements, e.g., suspected child abuse? Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects? Not 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. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research (See Attachment 1, AR-2, of this announcement, as posted on the CDC Web site). 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.

(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.

g. Study Samples—Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the referral sources been described, including the definitions and criteria? What plans have been made to include women and minorities and their subgroups as appropriate for the scientific goals of the research? How will the applicant deal with recruitment and retention of subjects?

h. Dissemination—What plans have been articulated for disseminating findings?

i. Measures of Effectiveness—The Peer Review Panel shall assure that measures set forth in the application are in accordance with CDC's performance plans. How adequately has the applicant addressed these measures?

The IRGRC will also examine the appropriateness of the proposed project budget and duration in relation to the proposed research and the availability of data required for the project.

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

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

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

c. The significance of the proposed activities in relation to the priorities and objectives stated in "Healthy People 2010," the Institute of Medicine report, "Reducing the Burden of Injury," and the "CDC Injury Research Agenda." (See Attachment 2, Resource Materials, of this announcement, as posted on the CDC web site.)

d. Budgetary considerations.

3. Continued Funding.

Continuation awards made after FY 2003, but within the project period, will be made on the basis of the availability of funds and the following criteria:

a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual work plan and satisfactory progress is being demonstrated through presentations at work-in-progress monitoring workshops.

b. The objectives for the new budget period are realistic, specific, and measurable.

c. The methods described will clearly lead to achievement of these objectives.

d. The evaluation plan will allow management to monitor whether the methods are effective.

e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

## I. Other Requirements

### Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Annual progress report. The progress report will include a data requirement that demonstrates measures of effectiveness.

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

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

4. At the completion of the project, the grant recipient will submit a brief summary 2,500 to 4,000 words written in non-scientific [laymen's] terms. The narrative 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.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each see Attachment 1 of the program announcement, as posted on the CDC web site.

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 Requirement

- 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
- Executive Order 12372 does not apply to this program.

#### J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: <http://www.cdc.gov>. Click on "Funding," then "Grants and Cooperative Agreements."

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Cheryl Maddux, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2759, E-mail address: [afx0@cdc.gov](mailto:afx0@cdc.gov).

For program technical assistance, contact: Tom Voglesonger, Program Manager, Office of the Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-02, Atlanta, GA 30341-3724, Telephone: (770) 488-4823, E-mail address: [TVoglesonger@cdc.gov](mailto:TVoglesonger@cdc.gov).

Dated: February 1, 2003.

**Sandra R. Manning,**

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

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#### Attachment 1

#### Additional Requirements

##### AR-1

##### *Human Subjects Requirements*

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects. All awardees of CDC grants and cooperative agreements and their performance sites engaged in human subjects research must file an assurance of compliance with the Regulations and have continuing reviews of the research protocol by appropriate institutional review boards.

In order to obtain a Federal wide Assurance (FWA) of Protection for Human

Subjects, the applicant must complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. OHRP will verify that the Signatory Official and the Human Subjects Protections Administrator have completed the OHRP Assurance Training/Education Module *before* approving the FWA. Existing Multiple Project Assurances (MPAs), Cooperative Project Assurances (CPAs), and Single Project Assurances (SPAs) remain in full effect until they expire or until December 31, 2003, whichever comes first.

To obtain a FWA contact the OHRP at: <http://ohrp.osophs.dhhs.gov/irbasur.htm> OR If your organization is not Internet-active, please obtain an application by writing to: Office for Human Research Protections (OHRP), Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, MSC 7501, Rockville, Maryland 20892-7507.

**Note:** For Express or Hand Delivered Mail, Use Zip Code 20852

**Note:** In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

##### AR-2

##### *Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research*

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

##### AR-3

##### *Animal Subjects Requirements*

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant (as well as each

subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC-supported activities must file (or have on file) the Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC). Web page: <http://grants.nih.gov/grants/olaw>

##### AR-9

##### *Paperwork Reduction Act*

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant or a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

##### AR-10

##### *Smoke-Free Workplace Requirements*

CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

##### AR-11

##### *Healthy People 2010*

*CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. For the conference copy of "Healthy People 2010," visit the internet site: <<http://www.health.gov/>>healthypeople.*

##### AR-12

##### *Lobbying Restrictions*

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal Funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of CDC appropriated funds shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or

any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation or prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation.

It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

#### AR-13

##### *Prohibition on Use of CDC Funds for Certain Gun Control Activities*

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control." Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and

assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the language in the CDC's Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

#### AR-21

##### *Small, Minority, and Women-Owned Business*

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.
2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

#### AR-22

##### *Research Integrity*

The signature of the institution official on the face page of the application submitted under this Program Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in science."

The regulation places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity's (ORI) Assurance Program.

For examples: Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary (DHHS) that the applicant: (1) Has established an administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states that: "an applicant or recipient institution

shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary, \* \* \* and updated annually thereafter \* \* \* (2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

An additional policy is added in the year 2000 that "requires research institutions to provide training in the responsible conduct of research to all staff engaged in research or research training with PHS funds.

#### Attachment 2

##### *Definitions*

1. Individual injury research projects (R49's) are defined as research designed to:

- a. Elucidate the chain of causation—the etiology and mechanisms—of injuries and subsequent disabilities.
- b. Yield results directly applicable to identifying interventions to prevent injury occurrence or minimize disability
- c. Evaluate the effect of known interventions on injury morbidity, mortality, disability, and costs.

2. Injury is defined as physical damage to an individual that occurs over a short period of time as a result of acute exposure to one of the forms of physical energy in the environment, or to chemical agents, or the acute lack of oxygen. Excluded from this definition of injury are cumulative trauma disorders, musculoskeletal disorders of the back not caused by acute trauma, and effects of repeated exposure to chemical or physical agents. The three phases of injury control are defined as prevention, acute care, and rehabilitation. The major categories of injury are intentional, unintentional, and occupational. Intentional injuries result from interpersonal or self-inflicted violence, and include homicide, assaults, suicide and suicide attempts, child abuse and neglect (includes child sexual abuse), intimate partner violence, elder abuse, and sexual assault. Unintentional injuries include those that result from motor vehicle collisions, falls, fires, poisonings, drownings, recreational, and sports-related activities. Occupational injuries occur at the worksite and include unintentional trauma (for example, work-related motor-vehicle injuries, drownings, and electrocutions), and intentional injuries in the workplace.

##### *Resource Materials*

1. National Center for Injury prevention and Control. CDC Injury research Agenda. Atlanta (GA): Centers for Disease Control and Prevention; 2002. Internet Address: [http://www.cdc.gov/ncipc/pub-res/research\\_agenda/index.htm](http://www.cdc.gov/ncipc/pub-res/research_agenda/index.htm).

2. Reducing the Burden of Injury: Advancing Prevention and Treatment. Institute of Medicine, National Academy Press, 1999. 2101 Constitution Avenue, NW. Washington, DC 20418. Cost: \$27.96 Telephone 202-334-3313 Internet Address: <http://www.nap.edu/catalog/6321.html>.

**Attachment 3***Research Activities*

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 psycho social problems following injury.

Clinical preventive services for patients treated in emergency departments (ED), hospital trauma units, and other acute care settings can help reduce the risk of injury and mitigate the effects of injuries that do occur. Such services might include instruction in the proper use of safety restraints and screening and interventions for alcohol problems, intimate partner violence, or child abuse. For injured patients, ED visits and inpatient hospital admissions for trauma care may provide crucial opportunities for early identification of and intervention for post-traumatic stress disorder and other psycho social problems that can follow or be exacerbated by injury.

Decision makers are often reluctant to fund preventive clinical services because they believe the investment needed to implement a single service in one clinical setting is too high. Research should demonstrate the effectiveness and value of such services and examine ways to implement multiple services simultaneously to amortize operational costs. Medical staff from the clinical setting should be actively involved in carrying out this research.

2. Develop and apply methods that can be used to calculate population-based estimates of the incidence, prevalence, costs, and long-term consequences of SCI and non-hospitalized TBI.

Development and validation of methods is needed to assess and describe both the spectrum of outcomes following "mild" TBI and the magnitude of those outcomes. Such methods are lacking for some subgroups of people with TBI, particularly those with "mild" TBI. Research should focus on increasing uniformity of case identification methods to improve the comparability of national-level data for people with TBI. Considering available resources and the language in the TBI Act Re-Authorization for 2000, case identification for people with "mild" TBI, including those who do not receive medical care, should receive highest priority.

The NCIPC conducts population-based surveillance to develop nationally representative estimates of the incidence, prevalence, nature, and causes of injuries that result in long-term disability. This activity includes conducting population-based follow-up studies to identify and track the long-term outcomes of disabling injuries. Research should investigate the unique outcomes and special needs of specific subgroups of TBI and SCI populations, such as those violently injured. Better information about outcomes could improve estimates of the true burden of disability for individuals with "mild" TBI by helping to document long-term problems resulting from these injuries. These improved estimates should also include screening persons for previous history of TBI, including "mild" TBI. Research should also identify the service

needs of people with TBI and SCI, providing useful information for injured persons, service providers, and policy makers.

The direct medical costs and indirect costs associated with disabling injuries are not well documented; however, this information is important to guide decisions about resource allocation and other policies. For TBI, the study most often cited was published 10 years ago. Research should provide comprehensive, up-to-date information about the direct and indirect costs of TBI and SCI. In addition, research should estimate the costs associated with secondary conditions, e.g., pressure sores, depression, and alcohol abuse.

3. Identify methods and strategies to ensure that people with TBI and SCI receive needed services.

People disabled by an injury often do not receive the help they need. A CDC-funded follow-up study of TBI in Colorado found that one year after injury, about one third of people with a disability said they had not received any services since their discharge from the hospital. According to a 1998 General Accounting Office report, people who have cognitive or behavior problems, but not physical problems, resulting from TBI are among those most likely to have unmet service needs. Without treatment, people with behavior problems are the most likely to become homeless, be committed to mental institutions, or be sentenced to prison. A recent study showed that people with TBI who received the services they needed reported a better quality of life. Research should increase understanding of the gaps between needed and available services for people with TBI and SCI and should identify strategies to close those gaps. Development and validation of methods are needed to better identify persons with the mildest forms of central nervous system injury (including "mild" TBI) and to explore the possibility of using these identification methods to link these injured persons with services.

People with "mild" TBI may not even be diagnosed with a TBI, making it even more difficult for them to get assistance. Research should explore the possibility of adapting case identification methods to help link people with TBI and SCI to services. To that end, the Injury Center has already funded two small, pilot projects to investigate the feasibility of using state-based TBI surveillance to identify people hospitalized with TBI who may need help finding out about services. Studies should investigate specific methods for linking people to information and services, such as evaluating the usefulness of toll-free telephone numbers that serve as single points of entry to the service delivery system. Studies should also describe the spectrum of rehabilitation services and trends in service provision, and they should evaluate access to medical, rehabilitation, and social services to prevent disabling outcomes and secondary conditions.

**Attachment 4***Errata Sheet*

Special Instructions for PHS-398, Rev. 11/2002

**Announcement # PA Title****Section I—Preparing Your Application***B. General Instructions (Page 3)*

Use English only and avoid jargon and unusual abbreviations. Type the application.

**Format Specifications**

The Content section of the Program Announcement refers to "the narrative." The narrative should consist of items listed in the program announcement. Use only standard size fonts in black print that can be photocopied and easily read, do not use photo reduction or compressed print. Draw all graphs, diagrams tables, and charts in black ink. Do not include photographs, oversized documents, or materials that cannot be photocopied in the body of the application.

The ONLY item that should be used to keep the application together is a rubber band. Please do not use spiral binders, 3-ring notebooks, envelopes, binder clips, etc.

Do not submit an incomplete application. An application will be considered incomplete and returned if it is illegible, if it fails to follow the instructions, or if the material presented is insufficient to permit an adequate review. Unless specifically required by these instructions (e.g., human subjects certification, vertebrate animals verification, changes in other support), do not send supplementary or corrective material pertinent to the application after the receipt date without its being specifically solicited or agreed to by prior discussion with the Grants Management Specialist.

**Page Limitations and Content Requirements (Page 4)**

Disregard Page Limit under Research Plan, Sections a-d and adhere to the prescribed guidance in the Program Announcement.

*C. Specific Instructions**Budget Instructions (Page 11)*

CDC does not use the modular budget format. Disregard instructions regarding the dollar limitations. PHS 398 Form Page 4 and Form Page 5 are required to be submitted by all applicants regardless of the dollar amount requested.

Human Subject Research (Section 8.e., Pages 18–19)

Ensure that the application addresses the issue of Women and Minority Inclusion in Research Involving Human Subjects. The application could be determined as non-responsive if this issue is not covered within the research plan.

**Section II—Submitting Your Application**

Send the Application to the following address: Technical Information Management—PA#, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341–4146. *Please do not send the application to the National Institutes of Health.*



Disregard all instructions under Section A. INSTRUCTIONS (Page 31)

Disregard Sections B–D (Pages 34–35). Please refer to the Program Announcement, “Evaluation Criteria” section, for the applicable CDC review process.

Disregard Section M, First Paragraph (Pages 53–54); Section N (Pages 54–55) and Section O (Pages 55–56); and all pages following Page 56.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03033]

#### Grants for Dissemination Research of Effective Interventions To Prevent Unintentional Injuries; Notice of Availability of Funds

*Application Deadline:* April 8, 2003.

#### A. Authority and Catalog of Federal Domestic Assistance Number

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 Health Service Act, as amended. The catalog of Federal Domestic Assistance number is 93.136.

#### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for grants for Dissemination Research of Effective Interventions to Prevent Unintentional Injuries. This program addresses the “Healthy People 2010” focus area of Injury and Violence Prevention.

The purposes of the program are to:

1. Solicit research applications that address the priorities reflected under the “Programmatic Requirements.”
2. Build the scientific base for the prevention and control of injuries, disabilities, and deaths.
3. Encourage professionals from a wide spectrum of disciplines of engineering, epidemiology, medicine, biostatistics, public health, law and criminal justice, behavioral, and social sciences to perform research in order to prevent and control injuries more effectively.
4. Encourage investigators to propose research that involves intervention development and testing as well as research on methods; to encourage individuals, organizations, or communities to adopt and maintain effective intervention strategies.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC): Develop new or improved approaches for preventing and controlling death and disability due to injuries.

#### C. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions and institutes, hospitals, managed care organizations, other public and private nonprofit and for-profit organizations, faith-based organizations, State and local governments or their *bona fide* agents, including 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, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and/or women-owned businesses.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration:

1. A principal investigator who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing injury prevention and dissemination research in peer-reviewed journals.
3. Effective and well-defined working relationships within the performing organization and with outside entities which will ensure implementation of the proposed activities.
4. The ability to carry out injury prevention and dissemination research projects as defined under Attachment 2 (1.a–c). The attachment is posted with this announcement on the CDC Web site: <http://www.cdc.gov/ncipc/ncipchm.htm>.
5. The overall match between the applicant's proposed theme and research objectives, and the program interests as described under the heading, “Program Requirements.”

#### D. Funding

##### Availability of Funds

Approximately \$450,000 is available in FY 2003 to fund two awards for this grant program. It is expected that the awards will begin on or about September 1, 2003, and will be made for a 12-month budget period within a project period of up to three years. The maximum funding level for each project will not exceed \$225,000 (including both direct and indirect costs) per year or \$675,000 for a three-year project period.

Applications that exceed the funding caps noted above will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

Consideration will also be given to current grantees who submit a competitive supplement requesting one year of funding to enhance or expand existing projects, or to conduct one-year pilot studies. These awards will not exceed \$150,000, including both direct and indirect costs. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant and are based on the availability of funds.

Continuation awards made after FY 2003, but within the approved project period, will be made on the basis of the availability of funds and the following criteria:

- a. The accomplishments reflected in the progress report of the continuation application indicate that the applicant is meeting previously stated objectives or milestones contained in the project's annual work plan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.
- b. The objectives for the new budget period are realistic, specific, and measurable.
- c. The methods described will clearly lead to achievement of these objectives.
- d. The evaluation plan will allow management to monitor whether the methods are effective.
- e. The budget request is clearly explained, adequately justified, reasonable and consistent with the intended use of grant funds.

##### Use of Funds

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.