Dated: December 15, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97–33253 Filed 12–19–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Assessment of Medical Technology

The Agency for Health Care Policy and Research (AHCPR), through the Center for Practice and Technology Assessment (CPTA), announces that it is initiating an assessment of the effectiveness of Prostate-specific antigen (PSA) testing in patients with benign prostatic hyperplasia (BPH).

The AHCPR is requesting information on the utility, and costs associated with the use of PSA testing and the specific indications for which this testing is appropriate. The AHCPR also requests information on patient selection criteria.

The assessment consists of a synthesis of information found in published literature and obtained from appropriate organizations in the private sector, Public Health Service (PHS) agencies and others in the Federal Government. AHCPR assessments are conducted in accordance with sections 904(b) and (d) of the PHS Act (42 U.S.C. 299a–2(b) and (d)). The assessment is based on the most current knowledge concerning the clinical effectiveness and appropriate uses of the technology being evaluated. The information being sought by this notice is a review and evaluation of past, current, and planned research related to this technology, as well as a bibliography of published, controlled clinical trials and other well-designed clinical studies. Information related to the characteristics of the patient population most likely to benefit from PSA testing as well as information on the clinical acceptability, effectiveness, and the extent of use of this technology, is also being sought. Following completion of the assessment, a recommendation will be formulated to assist the Health Care Financing Administration (HCFA) in establishing Medicare coverage policy.

The AHCPR is interested in receiving information which would help in the evaluation or review of the technology as described above. To enable the interested scientific community to evaluate the information and analysis included in the assessment, AHCPR will discuss in the assessment only those data and analyses for which a source(s) can be cited. Respondents are therefore encouraged to include with their submissions a written consent permitting AHCPR ''to cite and make public the sources of the data and the comments provided''. Otherwise, in accordance with the confidentiality statute governing information collected by AHCPR, 42 U.S.C. 299a–1(c), no information received will be published or disclosed which could identify an entity or individual supplying the information or any individual or entity described in the information. In addition, clearly market proprietary information may be kept confidential in accordance with the Freedom of Information Act, 5 U.S.C. § 552(b)(4).

Any person or group wishing to provide AHCPR with information relevant to this assessment should do so in writing no later than March 23, 1998 to: Douglas B. Kamerow, M.D., M.P.H., Director, Center for Practice and Technology Assessment, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Suite 310, Rockville, MD 20852, Phone: (301) 594–4015.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Number 816]

Individual Grants for Extramural Injury Research for Primary Prevention of Unintentional Injuries, Acute Care, Disability Prevention, and Biomechanics; Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC) announces that applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 1998.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Unintentional Injuries. (To order a copy of Healthy People 2000, see the Section Where to Obtain Additional Information.)

Authority

This program is authorized under Sections 301, 391–394 of the Public Health Service Act (42 USC 241, 280b–280b–3), as amended. Program regulations are set forth in Title 42 CFR Part 52.

Smoke-Free Workplace

CDC strongly encourages all grant and cooperative agreement recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and 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, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include all nonprofit and for-profit organizations. Thus State and local health departments and State and local governmental agencies, universities, colleges, research institutions, and other public and private organizations, including small, minority and/or woman-owned businesses are eligible for these research grants. Current holders of CDC injury control research projects are eligible to apply.

Note: An organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, a grant, contract, loan, or any other form.

Availability of Funds

Approximately $2.7 million is available for FY 1998 injury research grants that include funding for projects that address primary prevention of unintentional injuries (home and leisure, and motor vehicle related-injuries), acute care, the prevention of secondary conditions in persons with disabilities, and biomechanics.

Approximately $1,800,000 is available to support 6–8 projects that address primary prevention of unintentional injuries (home and leisure, and motor vehicle related-injuries), acute care, and the prevention of secondary conditions in persons with disabilities. Awards will be made for a 12-month budget period within a project period not to exceed three years. The maximum funding level per year will not exceed $300,000 (including both direct and indirect costs). Applications that exceed the funding cap of $300,000 will be excluded from the competition and returned to the applicant.

Approximately $900,000 is available to support 3–5 projects that address

biomechanics. Awards will be made for a 12-month budget period within a project period not to exceed three years. The maximum funding level per year will not exceed $300,000 (including both direct and indirect costs). Applications that exceed the funding cap will be excluded from the competition and returned to the applicant.

The specific program priorities for these funding opportunities are outlined with examples in this announcement under the subheading, ''Programmatic Priorities.''

Continuation awards within the 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 workplan milestones reflected in the continuation application, and the availability of Federal funds. In addition, if funds are available, continuation awards may be eligible for increased funding to offset inflationary costs.

Use of Funds-Restrictions on Lobbying

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. 1352 (which has been in effect since December 23, 1989), recipients (and their subtier 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, the current HHS Appropriations Act expressly prohibits the use of appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of the law provides as follows:

Section 503(a) No part of any appropriation contained in this Act 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 legislature, except in presentation to the Congress or any State legislature itself .

(b) No part of any appropriation contained in this Act 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 legislature.

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, 1998, 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.

Background and Definitions

A. Background

By nearly every measure, injury ranks as one of the nation's most pressing health problems. More than 150,000 people die each year as a result of motor vehicle crashes, falls, fires, drownings, poisonings, suicides, homicides, and other types of injuries. Each year, 56 million people sustain injuries severe enough to require medical treatment, and for every 100 people injured, the effects are serious enough to require 162 days of restricted activity. Thirty-four million injured persons visit emergency departments and another 2.7 million are hospitalized.

Injury is the leading cause of death for Americans between the ages of one and 44 years, and the leading cause of potential years of life lost. Young children are at the greatest risk from car crashes (both as occupants and pedestrians), drownings, and fires. Adolescents and young adults, especially males, are at highest risk of death from motor-vehicle crashes and gunshot wounds. For people older than 75, falls are the leading cause of death.

Although the greatest cost of injury is in human suffering and loss, the financial cost of injury is estimated at more than $224 billion, an increase of 42 percent in the last decade. These costs include direct medical care and rehabilitation costs as well as lost wages of the individual and productivity losses to the nation.

Opportunities to understand and prevent unintentional injuries and reduce their effects are available. Maximizing these opportunities for prevention and control requires a broad approach which will incorporate many disciplines that previously have not been an integral part of public health efforts. Many of these opportunities and research priorities are identified in Healthy People 2000; Injury in America (National Academy Press, 2101 Constitution Avenue, NW, Washington, D.C. 20418—ISBN0–309–03545–7); Injury Prevention: Meeting the Challenge (supplement to the American Journal of Preventive Medicine, (Vol. 5, no. 3, 1989); and Cost of Injury (Dorothy P. Rice, Ellen J. MacKenzie, and Associates, Cost of Injury: A Report to the Congress, San Francisco, California: Institute for Health and Aging, University of California and Injury Prevention Research Center, The Johns Hopkins University, 1989).

B. Definitions

1. 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. The three phases of injury control are defined as prevention, acute care, and rehabilitation. Within these phases 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, elder and child abuse, violence against women, and sexual assault. Unintentional or unintended injuries include those that result from motor vehicle collisions, falls, fires, poisonings, and drownings. Occupational injuries occur at the worksite and include unintentional trauma such as work-related motor-vehicle injuries, drownings, electrocutions, and intentional injuries in the workplace such as homicide. Not included in this definition of occupational injuries are cumulative

trauma disorders, back injuries not caused by acute trauma, and effects of repeated exposures to chemical or physical agents.

2. Individual injury control research projects (R01) are defined as research designed to:

a. Elucidate the chain of causation—the etiology and mechanisms—of injuries and subsequent disabilities; or

b. Yield results directly applicable to identifying interventions to prevent injury occurrence or minimize disability; or

c. Evaluate the effect of known interventions on injury morbidity, mortality, disability, and costs.

Purpose

The purposes of this program are to:

A. Support injury prevention and control research on priority issues as delineated in Healthy People 2000; Injury in America; Injury Prevention: Meeting the Challenge; and Cost of Injury.

B. Encourage professionals from a wide spectrum of disciplines such as engineering, medicine, health care, public health, behavioral and social sciences, and others, to undertake research to prevent and control injuries.

C. Expand the development and evaluation of current or new intervention methods and strategies for preventing unintentional injuries.

D. Build the scientific base for the prevention of unintentional injuries and deaths.

Program Requirements

The following are applicant requirements:

A. 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.

B. Demonstrated experience (on the applicant's project team) in conducting, evaluating, and publishing in peer-reviewed journals injury control research (as previously defined).

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

D. The ability to carry out an injury control research project as previously defined under Background and Definitions, (B.2.a-c).

E. The overall match between the applicant's proposed theme and research objectives and the program priorities as described under the heading ''Programmatic Priorities.''

Note: Grant funds will not be made available to support the provision of direct care services. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement) as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Priorities

Grant applications for research projects that address primary prevention of unintentional injuries (home and leisure, and motor vehicle related-injuries), acute care, the prevention of secondary conditions in persons with injury-related disabilities, and biomechanics are sought. The focus of grants should reflect the broad-based need to control injury morbidity, mortality, disability, and costs.

Applications must address a programmatic priority area as noted below. Examples of possible projects listed under the priority areas below are not exhaustive. Innovative alternative approaches are encouraged.

For *primary prevention of unintentional injuries*, there is programmatic interest in the areas of home and leisure, and motor vehicle injuries:

(1) Specifically, there is special programmatic interest in the development and evaluation of unintentional injury prevention strategies that can be applied in inpatient and outpatient clinical and/or managed care settings (e.g., HMOs, PPOs, clinics, clinicians' offices, academic health centers, etc.). For example, health care-based programs that reduce the injury risk to elderly drivers with medical conditions, fall prevention programs among the elderly, and other methods of delivering injury prevention through clinical practice or managed care settings, are acceptable.

(2) There is interest in applying behavioral research to injury prevention science. That is, the application of behavior change strategies to injury problems. For example, applying ''stages-of-change'' or the transtheoretical model to modify behaviors that will increase the protection of motor vehicle occupants, testing peer-to-peer and cross-generational counseling approaches, applying elements of social learning theory or social cognitive theory to changing unintentional injury risk behaviors, or implementing interventions that take advantage of several theoretical approaches simultaneously are acceptable.

(3) There is programmatic interest in research that evaluates the effects of making low-cost safety devices more available and or accessible to special and general populations. There is interest, as well, in the use of economic incentive systems, such as discounts and rebates, or through insurance programs (health, automobile or life). For example, these approaches could be studied as methods for increasing the use and maintenance of residential smoke detectors or sprinkler systems in high risk or rural neighborhoods, or to promote bicycle helmet ownership and use at the community level.

Community based research is particularly relevant, and studies that replicate successful programs in new settings or with other populations are eligible.

Unintentional injury prevention proposals primarily addressing the epidemiology of unintentional injuries will not be funded under this announcement.

A more thorough discussion of methodologies for conducting prevention effectiveness research is presented in ''A Framework for Assessing the Effectiveness of Disease and Injury Prevention,'' (CDC Morbidity and Mortality Weekly Report, March 27, 1992, Volume 41, Number RR–3, pp. 5–11) and in ''Assessing the Effectiveness of Disease and Injury Prevention Programs: Costs and Consequences'[5] (CDC Morbidity and Mortality Weekly Report, August 18, 1995, Vol. 44, No. RR10). To receive information on these reports see the section Where to Obtain Additional Information.

In *acute care* there is programmatic interest in intensifying the role of the hospital emergency department and inpatient hospital trauma services in public health surveillance (e.g., emergency department surveillance systems, inpatient trauma registries), clinical prevention services (e.g., protocols, interventions, and referrals for patients injured in interpersonal violence or identified as alcohol drinkers who drink at a hazardous level), evaluation of acute care effectiveness and costs (e.g., studies of trauma care systems in terms of their impact on morbidity and disability, assessments of treatment modalities that are used conventionally or are emerging rapidly in mainstream clinical practice).

(1) There is interest in establishing electronic linkages and common data elements across clinical information and public health surveillance systems (e.g., incorporating NCIPC's Data Elements for Emergency Department Systems, Release 1.0 in distributed record systems) to facilitate reporting of injury incidence and outcome data. There is interest in developing or further refining measures of injury severity (e.g., indices that stratify injuries by anatomic severity to facilitate evaluation of

trauma care processes and outcomes. Acute care-based, public health surveillance systems are most valuable where they provide comprehensive coverage of defined populations, are used to identify injury causes, risk factors, treatments and outcomes, and lend themselves to developing or refining clinical and epidemiologic measures of injuries including their severity and costs. Information on obtaining Data Elements for Emergency Department Systems, Release 1.0, can be found under the section Where to Obtain Additional Information.

(2) There is interest in evaluating the effectiveness and costs of programs that identify patients at high risk for subsequent injury and provide on-site interventions or referrals to further define the role of clinical prevention services in acute care settings. There is interest in research that evaluates ways to overcome barriers to service provision in emergency departments and inpatient trauma services to encourage greater use of clinical prevention services shown to be effective and economical. Acute care practitioners are uniquely positioned to help reduce or eliminate injury risk factors in the patient populations they serve. In emergency departments and inpatient trauma services there are opportunities to introduce or extend clinical prevention services (e.g., screening and brief intervention for patients with mild to moderate alcohol problems and identification and referral of patients with severe alcohol problems to specialized alcohol treatment services).

(3) There is interest in comprehensive evaluations of the effectiveness of trauma care systems (e.g., baseline and follow-up study of State or regional trauma care systems that identifies the system's impact on special populations such as children and the elderly as well as overall system effectiveness). There is interest in systematic studies in people of standard ways of delivering acute care as well as new interventions, particularly where key questions persist about benefits, risks, and costs (e.g., clinical trials of procedures, medications, or protocols used in trauma care). Systematic, empirically-based studies of effectiveness and costs are needed to evaluate poison control systems, trauma care systems, and specific diagnostic and therapeutic interventions currently used or rapidly emerging in acute care of injured persons.

In *disability prevention*, there is programmatic interest in community-based research to prevent the occurrence and reduce the severity of disabilities or other adverse outcomes among persons with traumatic brain injury (TBI) and spinal cord injury (SCI). Adverse outcomes include secondary conditions such as pressure ulcers and contractures; cognitive, behavioral, or psychological disorders; and other definable conditions associated with TBI or SCI. Research topics relating to TBI or SCI must include any of the following:

(1) Identifying risk factors associated with adverse outcomes following rehabilitation.

(2) Developing or evaluating interventions that are delivered in the community setting or as part of outpatient rehabilitation care to prevent or minimize the impact of adverse outcomes or secondary conditions.

(3) Defining the incidence of and adverse outcomes associated with mild TBI (i.e., nonfatal TBI not resulting in hospitalization) in a defined geopolitical population. Research proposals may address all age groups or may be limited to children and adolescents. Alcohol and drug use or dependence can be among a range of outcomes considered, but should not be the primary focus of the project.

(4) Defining patterns of post acute care among persons with SCI or TBI resulting in hospitalization, using population-based data. The evolving nature of health care delivery may have changed the availability of rehabilitation, the location where rehabilitative services are delivered, the timing of services received, and the length of the rehabilitation period. Research in this area should define the type of facility where rehabilitation services are received, timing of rehabilitation service delivery, length of rehabilitation period, and payment source for services.

Disability prevention proposals primarily addressing alcohol and other drug use or dependence will not be funded under this announcement.

In *biomechanics*, there is programmatic interest in traumatic brain and spinal cord injury (TBI/SCI). This interest includes the biomechanical evaluation of intervention concepts and strategies (e.g., multi-use recreational helmets, mouth and face protection devices for athletes, energy-absorbing playground surfaces, hip pads, motor vehicle side impact and rollover countermeasures, etc.). There is special interest in defining human tolerance limits for injury among very young children, women, and older persons; the development of biofidelic models to elucidate injury physiology and pharmacologic, surgical, rehabilitation, and other interventions; improvements in injury assessment technology; understanding impact injury mechanisms; and quantifying injury-related biomechanical responses for critical areas of the human body (e.g., brain and vertebral injury with spinal cord involvement). Consideration will also be given to the biomechanics of thoracic and abdominal viscera, musculature and joints including the articular cartilage, tendons and ligaments.

Reporting Requirements

An original and two copies of the financial status and progress reports are due 90 days after the end of each budget period. Final financial status and progress reports are due 90 days after the end of the project period.

Application Content

Applications for injury control research grants should include:

A. 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 2000; Injury In America; Injury Prevention: Meeting the Challenge; and Cost of Injury and should seek creative approaches that will contribute to a national program for injury control.

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

C. 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.

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

E. A description of all the project staff regardless of their funding source. It should include their title, 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.

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

G. 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.

H. A detailed first year's budget for the grant with future annual projections, if relevant. Awards will be made for project periods of up to three years.

I. Applicants must identify the principal injury phase (prevention, acute care, rehabilitation) discipline

(biomechanics, epidemiology) or type of injury (intentional, unintentional) upon which their project focuses.

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

Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the previous heading, Program Requirements (A–E). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. Applications that are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review (triage); the 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. Awards will be made based on priority score ranking by the Injury Research Grants Review Committee (IRGRC), programmatic priorities and needs as determined by the Advisory Committee for Injury Prevention and Control, and the availability of funds.

A. The first review will be a peer review conducted by the IRGRC on all applications. Factors to be considered will include:

1. The specific aims of the research project, i.e., the broad long-term objectives, the intended accomplishment of the specific research proposal, and the hypothesis to be tested.

2. The background of the proposal, i.e., the basis for the present proposal, the critical evaluation of existing knowledge, and specific identification of the injury control knowledge gaps which the proposal is intended to fill.

3. The significance and originality from a scientific or technical standpoint of the specific aims of the proposed research, including the adequacy of the theoretical and conceptual framework for the research.

4. For competitive renewal applications, the progress made during the prior project period. For new applications, (optional) the progress of preliminary studies pertinent to the application.

5. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures, plan for data management, and statistical analysis plan.

6. The extent to which the research findings will lead to feasible, cost-effective injury interventions.

7. The extent to which the evaluation plan will allow the measurement of progress toward the achievement of the stated objectives.

8. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities.

9. The degree of commitment and cooperation of other interested parties (as evidenced by letters detailing the nature and extent of the involvement).

10. The reasonableness of the proposed budget to the proposed research and demonstration program.

11. Adequacy of existing and proposed facilities and resources.

B. The second review will be conducted by the Advisory Committee for Injury Prevention and Control. The factors to be considered will include:

1. The results of the peer review.

2. The significance of the proposed activities in relation to the priorities and objectives stated in Healthy People 2000; Injury in America; Injury Prevention; Meeting the Challenge; and Cost of Injury.

3. National needs.

4. Program balance among the three phases of injury control: prevention, acute care, and rehabilitation; the major disciplines of injury control: biomechanics and epidemiology; target populations (e.g., adolescents, children, racial and ethnic minorities, rural residents, farm families, and people with low incomes); and

5. Budgetary considerations.

C. Continued Funding:

Continuation awards made after FY 1998, but within the project period, will be made on the basis of the availability of funds and the following criteria:

1. 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 workplan and satisfactory progress demonstrated through presentations at work-in-progress monitoring workshops.

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

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

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

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

Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.136.

Other Requirements

A. Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

B. Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

C. Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC

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.

In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. 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, Friday, September 15, 1995, pages 47947–47951.

D. Paperwork Reduction Act

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

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Specialist (whose address is reflected in section B, ''Applications''). It should be postmarked no later than two months prior to the planned submission deadline, (e.g., January 26 for February 25 submission). The letter should identify the announcement number, name the principal investigator, and specify the injury phase or discipline addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS–398 and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies on or before February 25, 1998 to: Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305.

C. Deadlines

1. Applications shall be considered as meeting the deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and are received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

2. Applications that do not meet the criteria above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

Application Packet

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement #816. CDC will not send application kits by facsimile or express mail. Please refer to Announcement #816 when requesting information and submitting an application.

Internet

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is [http://www.cdc.gov]. For your convenience, you may be able to retrieve a copy of the PHS Form 398 from [http://www.nih.gov80/grants/funding].

Business Management Technical Information

If you need further assistance after reviewing the contents of the documents business management information may be obtained from Lisa Tamaroff, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6796 or Internet:lgt1@cdc.gov.

Programmatic Technical Assistance

If you have programmatic question you may obtain information from Ted Jones, Program Manager, Extramural Research Grants Branch, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Mailstop K–58, 4770 Buford Highway, NE., Atlanta, GA 30341–3724, telephone (770) 488–4824, Internet: tmj1@cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

The document, ''Data Elements for Emergency Department System, Release 1.0'', and subsequent revisions can be found at the National Center for Injury Prevention and Control Web site: http://www.cdc.gov/ncipc/pub-res/deedspage.htm.

Information for obtaining copies of Injury in America (National Academy Press, 2101 Constitution Avenue, NW, Washington, DC 20418—ISBN0–309–03545–7); Injury Prevention: Meeting the Challenge (supplement to the American Journal of Preventive Medicine, (Vol. 5, no. 3, 1989); Cost of Injury (Dorothy P. Rice, Ellen J. MacKenzie, and Associates, Cost of Injury: A Report to the Congress, San Francisco, California: Institute for Health and Aging, University of California and Injury Prevention Research Center, The Johns Hopkins University, 1989); A Framework for Assessing the Effectiveness of Disease and Injury Prevention,'' (CDC Morbidity and Mortality Weekly Report, March 27, 1992, Volume 41, Number RR–3, pp. 5–11); and in ''Assessing the Effectiveness of Disease and Injury Prevention Programs: Costs and Consequences'' (CDC Morbidity and Mortality Weekly Report, August 18, 1995, Vol. 44, No. RR10) is included on a separate sheet with the application kit.

Dated: December 16, 1997.

Joseph R. Carter,

Acting Associate Director, Management and Operations, Centers for Disease Control and Prevention (CDC).

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