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[Announcement Number 723]

Grants for Intimate Partner Violence Prevention Research Notice of Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC) announces applications are being accepted for Intimate Partner Violence Prevention Research Grants for fiscal year (FY) 1997. The 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 Violent and Abusive Behavior. (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, 392, 393 and 394 of the Public Health Service Act, as amended (42 U.S.C. 241, 280b, 280b-1, 280b-1a, and 280b-3). Program regulations are set forth in Title 42 CFR, Part 52.

Eligible Applicants

Eligible applicants include all non-profit and for-profit organizations. Thus State and local health departments, 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.

Smoke-Free Workplace

CDC strongly encourages all grant 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, child care, health care, and early childhood development services are provided to children.

Availability of Funds

Approximately \$750,000 is expected to be available to fund 3-4 injury research grants in the area of intimate partner violence. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Priorities." It is expected that the awards will begin on or about September 1, 1997, and will be made for a 12-month budget period within a project period of up to three years. Funding may not exceed \$250,000 per year (including both direct and indirect costs). Grant applications that request more than the \$250,000 per year cap will be returned to the investigator as non-responsive. Funding availability may vary and is subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress demonstrated by investigators at work-in-progress monitoring workshops, the achievement of workplan milestones reflected in the continuation application, and the availability of Federal funds. In addition, continuation awards will be eligible for increased funding to offset inflationary costs depending upon the availability of funds.

Use of Funds: 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, 1997 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 new language in the CDC's 1997 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

Intimate partner violence is a major public health problem. Although men are at much greater risk of fatal injury due to interpersonal violence, women are at much higher risk of nonfatal injuries due to intimate partner violence. National surveys estimate that approximately 2 million women each year are battered by an intimate partner, and crime data from the Federal Bureau of Investigation (FBI) record about 1,500 murders of women by husbands or boyfriends each year. The Bureau of Justice Statistics reports that women sustained about 3.8 million assaults and 500,000 rapes a year in 1992 and 1993: More than 75 percent of these violent acts were committed by an intimate, a husband, ex-husband, boyfriend, or ex-boyfriend. Studies estimate that between 13 and 25 percent of all U.S. women will experience rape in their lifetimes.

These numbers are thought to be underestimates of the actual number of American women assaulted by intimate male partners.

The total extent and severity of violence-related nonfatal injuries is unknown, but an increasing portion of the nation's health care and rehabilitation systems' resources are devoted to attending to victims of violence. Intimate partner violence (including rape, physical battering, and psychological abuse) are associated with a host of both short-and long-term problems, including physical injury and illness, psychological symptoms, and death. The consequences extend far beyond the individual female victims, affecting their children, families, friends, and society as well.

Opportunities to understand and prevent intimate partner violence-related injuries and reduce their effects are available. Maximizing these opportunities for prevention requires a broad approach, incorporating many disciplines that heretofore have not been an integral part of public health efforts. Many of these opportunities and research priorities are discussed in Injury Control in the 1990s: A National Plan for Action. Atlanta: Centers for Disease Control and Prevention, 1993 and Healthy People 2000. Additional background information can be found in the following suggested readings: Understanding Violence Against Women, Violence and the Public's Health, Understanding and Preventing Violence, and Violence in America: A Public Health Approach. (To receive information on these reports see the

section Where To Obtain Additional Information);

B. Definitions

1. *Injury*: Injury is generally 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.

2. *Intimate Partner Violence* is defined as threatened or actual use of physical or sexual violence or psychological/emotional abuse perpetrated on a woman by a partner or ex-partner that either results or has the potential to result in injury or death. Types of behavior that fit within this definition are commonly referred to as domestic violence, sexual assault, spouse abuse, date rape, partner abuse, women battering, and acquaintance rape. Public health approaches violence as a health issue and consequently, uses injuries, both fatal and nonfatal, psychological and physical, to quantify the impact of violence. Our primary interest is in preventing violence against adolescent and adult women that occurs in the context of intimate relationships.

3. *Intimate partner violence prevention research projects* are defined as research designed to:

- Elucidate the chain of causation—the etiology and mechanisms—of injuries related to intimate partner violence; or
- Yield results directly applicable to identifying interventions to prevent injuries and deaths due to intimate partner violence; or
- Evaluate the effect of policies, programs, or interventions for intimate partner violence on morbidity, mortality, disability, and costs.

Purpose

The purposes of this program are to:

- Build the scientific base for the prevention of injuries and deaths due to intimate partner violence as delineated in Injury Control in the 1990s: A National Plan for Action. Atlanta: Centers for Disease Control and Prevention, 1993 and Healthy People 2000.
- Identify effective strategies to prevent intimate partner violence-related injuries.
- Expand the development and evaluation of current and new intervention methods and strategies for the primary prevention of intimate partner violence-related injuries.
- Encourage professionals from a wide spectrum of disciplines such as medicine, health care, public health, criminology and criminal justice, and

behavioral and social sciences, to undertake research to prevent and control injuries from intimate partner violence.

E. Encourage the training of pre-doctoral minority investigators to work in the area of violence research.

Program Requirements

The following are applicant requirements:

A. A principal investigator who has conducted research, published the findings, and has specific authority and responsibility to carry out the proposed project.

B. Demonstrated experience in conducting, evaluating, and publishing injury control research on the applicant's project team.

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

D. Ability to carry out intimate partner violence prevention research as previously defined under Background and Definitions, (B.3.a-c).

E. 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

Applicants must propose research that (1) enhances understanding of social, economic, and environmental factors that may be associated with intimate partner violence, and (2) determines the effectiveness of prevention/intervention programs for perpetrators of intimate partner violence.

Enhance understanding of societal level factors within a specific targeted community that may be associated with intimate partner violence and the costs of such violence.

- Conduct research to determine which societal level factors (e.g., crowding, socioeconomic status (SES), norms about intimate partner violence, levels of general violence, number of liquor stores in the community, etc.) contribute to perpetration of intimate partner violence.
- Conduct studies to determine direct and indirect costs of intimate partner

violence (such as days absent from work or school, quality of life, numbers of visits to mental health and medical care providers, number of miscarriages, mental and physical disabilities, impact on child witnesses, etc.)

Determine the effectiveness of prevention/intervention programs for (potential or actual) perpetrators of intimate partner violence.

- Develop and evaluate innovative or alternative approaches or settings for identifying and providing interventions and/or deterrents for perpetrators of intimate partner violence.
- Identify the components of effective batterer interventions.
- Evaluate the effectiveness of programs targeting children and young adolescents that teach and foster healthy interpersonal relationships as primary prevention of future perpetration of intimate partner violence.

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. A brief (2–3 page) summary of the study findings and a final financial status report is 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 need 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 Injury Control in the 1990s: A National Plan for Action. Atlanta: Centers for Disease Control and Prevention, 1993 and Healthy People 2000 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 role and responsibilities of the project's principal investigator.

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 the role, duties, and responsibilities of the project's pre-

doctoral minority investigator(s) (a minimum of 15% of each pre-doctoral minority investigator's time should be reflected in the project's budget).

G. A description of those activities related to, but not proposed to be supported by the grant.

H. A description of the involvement of other entities, (e.g., proposed study sites), that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.

I. A detailed first year budget for the project with future annual projections, if relevant.

J. Applicants must identify in a cover letter one of the topics previously outlined under the heading Programmatic Priorities upon which their project is focused.

K. An explanation of how the research findings will lead to feasible, cost-effective injury interventions.

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 asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

Evaluation Criteria

Upon receipt, applications will be screened 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 which are complete and responsive may be subjected to a preliminary evaluation (triage) by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant a full review by the Injury Research Grants Review Committee (IRGRC); 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

scores assigned to applications by the IRGRC, programmatic priorities and needs determined by a secondary review committee (the Advisory Committee for Injury Prevention and Control), and the availability of funds.

A. The first review following the preliminary review (triage) will be a peer review to be conducted on all competitive 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 plans, plans for inclusion of minorities and both sexes.

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

7. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities, including pre-doctoral minority investigator(s).

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

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

10. Adequacy of existing and proposed facilities and resources.

11. An explanation of how the research findings will lead to feasible, cost-effective injury interventions.

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 objectives outlined under the section, 'Programmatic Priorities.'

3. National needs.

4. Overall distribution among:

- the major disciplines of violence-related injury prevention: social and behavioral science, biomechanics, and epidemiology;

- populations addressed (e.g., batterers, adolescents, racial and ethnic minorities, the elderly, children, urban, rural).

5. Budgetary considerations (e.g., preference may be given to applicants who submit proposals requesting funding for research projects of one to two years duration).

6. Additional consideration will be given to those applicants who provide evidence of an injury research training program for pre-doctoral minority investigators.

C. Continued Funding

Continuation awards 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 has been demonstrated through monitoring presentations or work-in-progress 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; and

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

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.

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.

Women and Minority Inclusion Policy

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, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. 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.

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 March 20, 1997. The letter should identify the announcement number, name the principal investigator, and specify the priority area of study the proposal addresses as outlined under the section Programmatic Priorities. 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 (OMB No. 0925-0001 Revised 5/95) 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 April 22, 1997, 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 321, Atlanta, Georgia 30305, telephone (404) 842-6796.

C. Deadlines

1. Applications shall be considered as meeting a 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 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 which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 723. You will receive a complete program description, information on application procedures, and application forms. Business management technical information may be obtained from Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, 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: <igt1.cdc.gov>.

Programmatic technical assistance may be obtained from Ted Jones, Project Officer, 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, Georgia 30341-3724, telephone (770) 488-4824, internet: <tmj1.cdc.gov>.

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>.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 723 when requesting information and submitting an application.

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, D.C. 20402-9325, telephone (202) 512-1800.

Copies of Injury Control in the 1990s: A National Plan for Action. Atlanta: Centers for Disease Control and Prevention, 1993 and 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, pages 5-11) may be obtained by calling (770) 488-4265.

Information for obtaining the suggested readings, Understanding Violence Against Women, Violence and the Public's Health, Understanding and Preventing Violence, and Violence in America: A Public Health Approach, is included on a separate sheet with the application kit.

Dated: February 11, 1997.

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

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Food and Drug Administration

[Docket No. 93F-0195]

Fish and Fishery Products Hazards and Controls Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the