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 - d. Budgetary considerations.
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 - b. The objectives for the new budget period are realistic, specific, and measurable.
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- AR-21 Small, Minority, and Women-owned Business

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Angela Webb, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement #01013, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770) 488-2784, Internet address: awebb@cdc.gov.

For program technical assistance, contact: Ted Jones, Program Manager, Office of Research Grants, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58, Atlanta, GA 30341-3724, Telephone (770) 488-4824, Internet address: tmj1@cdc.gov.

Dated: December 18, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01014]

Grants for Traumatic Injury Biomechanics Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 2001. This announcement is related to the Healthy People 2010 focus areas of Injury and Violence Prevention.

The purposes of this program announcement are to:

1. Solicit research applications that address the priorities reflected under the heading, "Programmatic Interests."

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

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

B. 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, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses.

Current holders of CDC R49 Research grants and R49 Injury Control Research Center (ICRC) grants are eligible to apply for supplemental funding to enhance or expand existing projects or to conduct one year pilot studies. Grantees currently funded under announcements 00024 (Grants for Injury Control Training and Demonstration Center) and 00043 (Grants for National Academic Centers of Excellence on Youth Violence Prevention) are not eligible to apply for supplements.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

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 Addendum 2, (1.a-c). The addendum is contained in the application package.
5. The overall match between the applicant's proposed theme and research objectives, and the program interests as described under the heading, "Programmatic Interests."

C. Availability of Funds

Approximately \$1.2 million is expected to be available in FY 2001 for

injury research grants to fund approximately four to five awards. The specific program priorities for these funding opportunities are outlined with examples in this announcement under the section, "Programmatic Interests."

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a three-year project period. The maximum funding level will not exceed \$300,000 (including both direct and indirect costs) per year or \$900,000 for the three-year project period. Those grantees eligible for supplemental funding may request up to \$150,000 (including both direct and indirect costs) for one year. Supplemental awards will be made for the budget period to coincide with the actual budget period of the grant. Applications that exceed the funding cap of \$300,000 per year will be excluded from the competition and returned to the applicant. The availability of Federal funding may vary and is subject to change.

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), and the achievement of workplan milestones reflected in the continuation application.

Note: Grant funds will not be made available to support the provision of direct care. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

Programmatic Interests

The National Center of Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research that will help expand and advance our understanding of injury causation. Traumatic injury biomechanics research is especially needed to understand the injury mechanisms that lead to long-term disability from brain and spinal cord injuries.

1. Research to advance the biomechanical understanding of traumatic brain and spinal cord injuries (TBI/SCI), thoracic and abdominal injuries resulting from blunt impact, and injuries occurring to the extremities and joints.

2. Evaluate, from a biomechanical perspective, intervention concepts and strategies such as multi-use recreational helmets, mouth- and face-protection devices for athletes, energy-absorbing

playground surfaces, hip pads, and motor vehicle side-impact and rollover countermeasures.

3. Define human tolerance limits for injury; develop biofidelic models to elucidate injury physiology as well as pharmacologic, surgical, rehabilitation, and other interventions; improve injury assessment technology; increase understanding of impact injury mechanisms; and quantify injury-related biomechanical responses for critical areas of the human body (e.g., brain and vertebral injury with spinal cord involvement).

Funding Preferences

While extending and adapting results and conclusions of the above efforts to the entire population is desirable, additional consideration will be given to proposals that emphasize research especially applicable to young children, women (and, in particular, pregnant women), and/or the elderly.

D. Application Content

Applications should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and 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 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 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.
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 with 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 five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; however, the subtotals must still be shown. In addition, the applicant must submit an additional copy of page 4 of Form PHS-398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

E. Submission and Deadline

Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter of intent shall be submitted on or before February 7, 2001, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. The letter should identify the announcement number, name 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.

Application Submission

Submit the original and five copies of PHS 398 (OMB Number 0925-0001 and adhere to the instructions on the Errata Instruction sheet for PHS 398). Forms are in the application kit.

On or before March 7, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Applications shall be considered as meeting the deadline if they are received at the above address on or before the deadline date; or sent on or before the deadline date, and received in time for submission to the independent review group. Applicants must 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 will not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria above are considered late applications, will not be considered, and will be returned to the applicant.

F. Evaluation Criteria

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 (triage) 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.

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 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 by a committee of no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) criteria to evaluate the methods and scientific quality of the application. 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?

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?

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 Work Group (SPRWG) from the ACIPC. The ACIPC Federal ex officio members 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). Federal ex officio members 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 Federal ex officio members to assure that research priorities of the announcement are understood and to provide background regarding current research activities.

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Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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