

service, procedure, or product represents the typical or ordinary experience of members of the public who use the service, procedure, or product, unless the representation is true, and competent and reliable scientific evidence substantiates that claim, or respondents clearly and prominently disclose either: (1) What the generally expected results would be for program participants; or (2) the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to achieve similar results.

Paragraph VI of the proposed order prohibits respondents from making any representation about the relative or absolute efficacy, performance, benefits, safety, or success of any ophthalmic service, procedure, or product purporting to treat, mitigate, or cure any refractive vision deficiency, unless the representation is true and, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph VII of the proposed order requires that proposed respondents: (1) Not disseminate to any optometrist or eye care provider any material containing any representations prohibited by the order; (2) send a required notice to each optometrist or eye care provider with whom proposed respondents have done business since January 1, 1994, requesting that the optometrist cease using any materials previously received from proposed respondents that contain any claims violative of the order, informing the optometrist of this settlement, and attaching a copy of this proposed compliant and order; (3) in the event that proposed respondents receive any information that subsequent to receipt of the required notice any optometrist or eye care provider is using or disseminating any advertisement or promotional material that contains any representation prohibited by the order, immediately notify the optometrist or eye care provider that proposed respondents will terminate the optometrist or eye care provider's right to market and/or perform PCM ortho-k if he or she continues to use such advertisements or promotional materials; (4) terminate any optometrist or eye care provider about whom proposed respondents receive any information that such person has continued to use advertisements or promotional materials that contain any representation prohibited by the order after receipt of the required notice; and

(5) for a period of three (3) years following service of the order, send the required notice to each optometrist or eye care provider with whom proposed respondents do business after the date of service of the order who has not previously received the notice; the notices shall be sent no later than the earliest of: (1) The execution of a sales or training agreement or contract between proposed respondents and the prospective optometrist or eye care provider; or (2) the receipt and deposit of payment from a prospective optometrist or eye care provider of any consideration in connection with the sale of any service or rights associated with PCM ortho-k. The mailing shall not include any other documents.

Paragraph VIII of the proposed order contains record keeping requirements for materials that substantiate, qualify, or contradict covered claims and requires the proposed respondents to keep and maintain all advertisements and promotional materials containing any representation covered by the proposed order. In addition, Paragraph IX requires distribution of a copy of the consent decree to current and future officers and agents. Further, Paragraph X provides for Commission notification upon a change in the corporate respondents. Paragraph XI requires proposed respondent J. Mason Hurt, O.D. to notify the Commission when he discontinues his current business or employment and of his affiliation with any new business or employment. The proposed order, in paragraph XII, also requires the filing of a compliance report.

Finally, Paragraph XIII of the proposed order provides for the termination of the order after twenty years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 97-22902 Filed 8-27-97; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 809]

Grants for Injury Control Research Centers; Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Control Research Centers (ICRCs) 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 areas of Violent and Abusive Behavior and 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, 392, 393, and 394 of the Public Health Service Act (42 U.S.C. 241, 280b, 280b-1, 280b-1a, and 280b-2). Program regulations are set forth in 42 CFR part 52.

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 Pub. L. 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

This announcement will provide funding for applicants in regions which do not have funded ICRCs and for applicants in regions which have funded centers which must re compete for funding.

Eligible applicants are limited to organizations in Region 1 (Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont), Region 2 (New Jersey, New York, Puerto Rico, Virgin Islands), Region 3 (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia), Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin), Region 6 (Louisiana, New Mexico, Oklahoma, Texas, Arkansas), and Region 8 (Colorado,

Montana, North Dakota, South Dakota, Utah, and Wyoming).

Eligible applicants include all nonprofit and for-profit organizations in Regions 1, 2, 3, 5, 6, and 8. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments, and small, minority and/or women-owned businesses are eligible for these grants. Applicants from non-academic institutions should provide evidence of a collaborative relationship with an academic institution.

The currently funded centers in Regions 4, 7, 9, and 10 are eligible for supplemental funding.

Note: ICRC grant awards are made to the applicant institution/organization, not the Principal Investigator.

Base funding (included in figures below)	Up to \$750,000.
One phase ICRC	Up to \$1,000,000.
(addresses one of the three phases of injury control)	
Two phase ICRC	Up to \$1,250,000.
(addresses two of the three phases of injury control)	
Comprehensive ICRC	Up to \$1,500,000.
(addresses all three phases of injury control)	

The existing funded centers in Regions 4, 7, 9, and 10 may submit proposals for supplemental awards to expand/enhance existing projects, to add a new phase(s) to an existing ICRC grant, or to add biomechanics project(s) that support one or more phases. The request should not exceed \$250,000 (direct and indirect cost) per year. Funding is subject to program need and 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

Availability of Funds

Approximately \$1,500,000 is expected to be available FY 1998 to fund at least two re-competing research centers or a combination of re-competing and new research center projects, depending on the outcome of the review process.

It is expected that the awards will begin on or around September 1, 1998, and will be made for a 12 month budget period within a project period of up to three years for developing research centers and five years for re-competing research centers.

Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

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

By nearly every measure, injury ranks as one of the nation's most pressing health problems. Injuries result from unintended events such as car crashes, falls, drownings, fires, and from intentional acts such as interpersonal violence and suicide. The annual toll includes the loss of more than 150,000 lives. Brain injury, spinal cord injury, and burns requiring extensive rehabilitative services number more than 400,000 annually. Injuries are the country's leading cause of years of potential life lost (YPLL) before age 65 (more than 3,600,000 YPLL annually in 1994). They are the leading cause of death and disability in children and young adults. Older Americans also suffer unduly from the severe consequences of injury. Many of the resources of the nation's health care system are devoted to attending to victims of injury, who occupy one of every eight hospital beds. Injury is also a primary cause of visits to physicians; it accounted for 66 million such visits in 1992. More than one-fourth of

Developing research center awards will not exceed \$500,000 per year (*total of direct and indirect costs*) with a project period not to exceed three years. Depending on availability of funds, re-competing research center awards may range from \$750,000 to \$1,500,000 per year (*total of direct and indirect costs*) with a project period not to exceed five years. The range of support provided is dependent upon the degree of comprehensiveness of the center in addressing the *phases of injury control* (i.e., *Prevention, Acute Care, and Rehabilitation*) as determined by the Injury Research Grants Review Committee (IRGRC).

Incremental levels within this range for successfully re-competing research centers will be determined as follows:

persons who visit emergency departments are seeking treatment for injuries. For the United States the aggregate lifetime cost of injuries occurring in 1994 was estimated to be \$224 billion.

As telling as it is, the litany of injury statistics ignores less quantifiable, but equally important concerns—pain and suffering, fear of injury among older persons, grief over loss or disablement of loved ones, and the inestimable societal loss of unrealized future contributions by children and young adults who suffer fatal or incapacitating injuries.

Fortunately, opportunities to understand and prevent injuries and reduce their effects are available. To exploit these opportunities will require a comprehensive approach to injury control, utilizing many disciplines that heretofore have not always been an integral part of public health efforts. However, it is not CDC's intention that all centers be individually comprehensive, but that the comprehensiveness of a priority-driven injury control effort be achieved in the national aggregate, building on the individual strengths and geographic balance of the various centers.

Many of these opportunities are discussed in the National Research Council and Institute of Medicine report, *Injury In America* (National Academy Press—ISBN 0-309-03545-7). Research priorities are also discussed in *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, San Francisco, California: Institute for Health and Aging, University of California, and Injury Prevention Research Center, The Johns Hopkins University, 1989), *Position Papers from The Third National Injury Control Conference* (Centers for Disease Control, Atlanta, Georgia, 1992), and *Injury Control in the 1990's: A National Plan for Action* (Centers for Disease Control and Prevention, Atlanta, Georgia, 1993). Information on these reports may be obtained from the individuals listed in the section Where to Obtain Additional Information.

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. 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, spouse abuse, elder abuse, and rape. 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. Not included in this definition of occupational injuries are cumulative trauma disorders, back injuries caused by acute trauma, and effects of repeated exposure to chemical or physical agents.

2. An *Injury Control Research Center (ICRC)* is defined as a scientifically-based organizational unit, generally, but not exclusively, established within an academic institution, which reports at an organizational level high enough to clearly demonstrate strong institutional support for the development of an interdisciplinary approach to the injury problem (e.g., dean of a school, university vice president, or commissioner of health).

A comprehensive ICRC is designed to allow the phases of injury control (i.e., research in prevention, acute care, and rehabilitation) to be addressed by a single organizational unit and managed

by an experienced research director (dedicated investigator at no less than 30 percent effort with an anticipated range of 30 percent-50 percent). The design of the core should be the basis on which both the research and practices of the ICRC are built, further allowing for in-depth application of key disciplines (e.g., physicians, epidemiologists, engineers, biomechanicists, social and behavioral scientists, biostatisticians, public health workers, and others) to the phases of injury control. Expertise (defined as: conducting ongoing high quality injury research and publication in peer reviewed scientific and technical journal(s)) from appropriate disciplinary groups must be included so as to address the injury problem phases chosen by the applicant.

A comprehensive ICRC can address all three phases of injury control within a single theme. For example, an ICRC with a rehabilitation theme can address prevention, acute care, and rehabilitation within the overall theme of rehabilitation.

A less comprehensive ICRC may be designed to allow one or two of the phases of the injury problem to be addressed by a single organizational unit; in such situations the remaining phase(s) of the injury problem may be addressed through collaborative arrangements with other institutions or organizations.

In keeping with CDC's mission as the nation's prevention agency, ICRC research is intended to progress from basic research to applied research to the development of interventions as described in: *Centers for Disease Control, A Framework for Assessing the Effectiveness of Disease and Injury Prevention*. *MMWR* 1992;41(RR-3).

While high quality research is to be considered an essential ingredient of the ICRC, equally important activities include: information gathering and dissemination; the ongoing provision of training opportunities to students, researchers, and voluntary, community-based, and State and local health department personnel; and implementation of projects relating to the development and evaluation of injury surveillance or injury prevention programs.

Purpose

The purposes of this program are:

A. To support injury prevention and control research on priority issues as delineated in: *Healthy People 2000*; *Injury Control in the 1990's: A National Plan for Action*; *Injury in America*; *Injury Prevention: Meeting the Challenge*; and *Cost of Injury: A Report to the Congress*;

B. To support ICRCs which represent CDC's largest national extramural investment in injury control research and training, intervention development, and evaluation;

C. To integrate collectively, in the context of a national program, the disciplines of engineering, epidemiology, medicine, biostatistics, public health, law and criminal justice, and behavioral and social sciences in order to prevent and control injuries more effectively;

D. To identify and evaluate current and new interventions for the prevention and control of injuries;

E. To bring the knowledge and expertise of ICRCs to bear on the development and improvement of effective public and private sector programs for injury prevention and control; and

F. To facilitate injury control efforts supported by various governmental agencies within a geographic region.

Program Requirements

The following are applicant requirements:

A. Applicants must demonstrate and apply expertise in at least one of the three phases of injury control (prevention, acute care, or rehabilitation) as a core component of the center. The second and/or third phases do not have to be supported by core funding but may be achieved through collaborative arrangements. Comprehensive ICRCs must have all three phases supported by core funding.

B. Applicants must document ongoing injury-related research projects or control activities currently supported by other sources of funding.

C. Applicants must provide a director (Principal Investigator) who has specific authority and responsibility to carry out the project. The director must report to an appropriate institutional official, e.g., dean of a school, vice president of a university, or commissioner of health. The director must have no less than 30 percent effort devoted solely to this project with an anticipated range of 30 to 50 percent.

D. Applicants must demonstrate experience in successfully conducting, evaluating, and publishing injury research and/or designing, implementing, and evaluating injury control programs.

E. Applicants must provide evidence of working relationships with outside agencies and other entities which will allow for implementation of any proposed intervention activities.

F. Applicants must provide evidence of involvement of specialists or experts in medicine, engineering, epidemiology,

law and criminal justice, behavioral and social sciences, biostatistics, and/or public health as needed to complete the plans of the center. These are considered the disciplines and fields for ICRCs. An ICRC is encouraged to involve biomechanicists in its research. This, again, may be achieved through collaborative relationships as it is no longer a requirement that all ICRCs have biomechanical engineering expertise.

G. Applicants must have an established curricula and graduate training programs in disciplines relevant to injury control (e.g., epidemiology, biomechanics, safety engineering, traffic safety, behavioral sciences, or economics).

H. Applicants must demonstrate the ability to disseminate injury control research findings, translate them into interventions, and evaluate their effectiveness.

I. Applicants must have an established relationship, demonstrated by letters of agreement, with injury prevention and control programs or injury surveillance programs being carried out in the State or region in which the ICRC is located. Cooperation with private-sector programs is encouraged.

Applicants should have an established or documented planned relationship with organizations or individual leaders in communities where injuries occur at high rates, e.g., minority health communities.

Grant funds will not be made available to support the provision of direct care. Studies may be supported which evaluate methods of care and rehabilitation for potential reductions in injury effects and costs. Studies can be supported which identify the effect on injury outcomes and cost of systems for pre-hospital, hospital, and rehabilitative care and independent living.

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.

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 final financial status and progress reports are due 90 days after the end of the project period.

Application Content

Applications for support of an ICRC should follow the PHS-398 (Rev. 5/95) application and Errata sheet, and should include the following information:

1. Face page.
2. Description (abstract) and personnel.
3. Table of contents.
4. Detailed budget for the initial budget period: The budget should reflect the composite figures for the grant as well as breakdown budgets for individual projects within the grant.
5. Budget for entire proposed project period including budgets pertaining to consortium/contractual arrangements.
6. Biographical sketches of key personnel, consultants, and collaborators, beginning with the Principal Investigator and core faculty.
7. Other support: This listing should include all other funds or resources pending or currently available. For each grant or contract include source of funds, amount of funding (indicate whether pending or current), date of funding (initiation and termination), and relationship to the proposed program.
8. Resources and environment.
9. Research plan including:
 - a. A proposed theme for the ICRC's injury control activities. The proposed activities should be clearly described in terms of need, scientific basis, expected interactions, and anticipated outcomes, including the expected effect on injury morbidity and mortality. In selecting the theme, applicants should consider the findings in *Injury In America* and the *Year 2000 Objectives for the Nation*.
 - b. A detailed research plan (design and methods) including hypothesis and expected outcome, value to field, and specific, measurable, and time-framed objectives consistent with the proposed theme and activities for each project within the proposed grant.
 - c. A detailed evaluation plan which should address outcome and cost-effectiveness evaluation as well as formative, efficacy, and process evaluation.
 - d. A description of the core faculty and its role in implementing and evaluating the proposed programs. The applicant should clearly specify how disciplines will be integrated to achieve the ICRC's objectives.
 - e. Charts showing the proposed organizational structure of the ICRC and its relationship to the broader institution of which it is a part, and, where applicable, to affiliate institutions or collaborating organizations. These charts should clearly detail the lines of authority as they relate to the center or the project, both structurally and operationally. ICRC's should report to an appropriate organizational level (e.g. dean of a school, vice president of a university, or commissioner of health), demonstrating strong institution-wide

support of ICRC activity and ensuring oversight of the process of interdisciplinary activity.

f. Documentation of the involved public health agencies and other public and private sector entities to be involved in the proposed program, including letters that detail commitments of support and a clear statement of the role, activities, and participating personnel of each agency or entity.

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 reviewed by CDC staff for completeness and responsiveness as outlined under the previous heading Program Requirements. 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 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.

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. Review by the Injury Research Grants Review Committee

Peer review of ICRC grant applications will be conducted by the IRGRC, which may recommend the

application for further consideration or not for further consideration. As a part of the review process the committee may conduct a site visit to the applicant organization for re-competing ICRCs. New applicants may be asked to travel to CDC for a meeting with the committee.

Factors to be considered by IRGRC include:

1. The specific aims of the application, e.g., the long-term objectives and intended accomplishments.
2. The scientific and technical merit of the overall application, including the significance and originality (e.g., new topic, new method, new approach in a new population, or advancing understanding of the problem) of the proposed research.
3. The extent to which the evaluation plan will allow for the measurement of progress toward the achievement of stated objectives.
4. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities.
5. The soundness of the proposed budget in terms of adequacy of resources and their allocation.
6. The appropriateness (e.g., responsiveness, quality, and quantity) of consultation, technical assistance, and training in identifying, implementing, and/or evaluating intervention/control measures that will be provided to public and private agencies and institutions, with emphasis on State and local health departments, as evidenced by letters detailing the nature and extent of this commitment and collaboration. Specific letters of support or understanding from appropriate governmental bodies must be provided.
7. Evidence of other public and private financial support.
8. Details of progress made in the application if the applicant is submitting a re-competing application. Documented examples of success include: development of pilot projects; completion of high quality research projects; publication of findings in peer reviewed scientific and technical journals; number of professionals trained; provision of consultation and technical assistance; integration of disciplines; translation of research into implementation; impact on injury control outcomes including legislation, regulation, treatment, and behavior modification interventions.

B. Review by CDC Advisory Committee for Injury Prevention and Control (ACIPC)

Factors to be considered by ACIPC include:

1. The results of the peer review.
2. The significance of the proposed activities as they relate to national program priorities and the achievement of national objectives.
3. National and programmatic needs and geographic balance.
4. Overall distribution of the thematic focus of competing applications; the nationally comprehensive balance of the program in addressing the three phases of injury control (prevention, acute care, and rehabilitation); the control of injury among populations who are at increased risk, including racial/ethnic minority groups, the elderly and children; the major causes of intentional and unintentional injury; and the major disciplines of injury control (such as biomechanics and epidemiology).
5. Budgetary considerations, the ACIPC will establish annual funding levels as detailed under the heading, Availability of Funds.

C. Applications for Supplemental Funding

Existing CDC Injury Centers may submit an application for supplemental grant awards to support research work or activities. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the ACIPC.

D. 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 of the current budget period show that the applicant's objectives as prescribed in the yearly workplans are being met;
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 allows management to monitor whether the methods are effective by having clearly defined process, impact, and outcome objectives, and the applicant demonstrates progress in implementing the evaluation plan;
5. The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of grant funds; and
6. Progress has been made in developing cooperative and collaborative relationships with injury surveillance and control programs implemented by State and local governments and private sector organizations.

Funding Preference

Special consideration will be given to re-competing Injury Control Research Centers. These centers as established and on-going and serve as a resource for Injury Control related issues for their States and regions.

Executive Order 12372 Review

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

Public Health System Reporting Requirements

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

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, 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.

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

In order to schedule and conduct site visits as part of the formal review process, potential applicants are encouraged to submit a nonbinding letter of intent to apply. It should be postmarked no later than one month prior to the submission deadline of October 5, 1997, for the application. The letter should be submitted to the Grants Management Specialist whose address is given in Part B of this Section. The letter should identify the relevant announcement number for the response, name the principal investigator, and specify the injury control theme or emphasis of the proposed center (e.g., acute care, biomechanics, epidemiology, prevention, intentional injury, or rehabilitation). The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently.

B. Applications

Applicants should use application Form PHS-398 (OMB No. 0925-0001 Revised 5/95) and adhere to the ERRATA Instruction Sheet contained in the Grant Application Kit. The narrative section for each project within an ICRC should not exceed 25 typewritten pages. Refer to the instruction in section 1, page 6, of PHS-398 for font type and size. *Applications not adhering to these specifications may be returned to applicant.*

Applicants must submit an original and five copies on or before November

5, 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 300, Atlanta, GA 30305.

C. Deadlines

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

1. Received on or before the deadline date; or
2. Sent on or before the deadline date and received in time for submission to the peer review committee. 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 mailing.

Applications which do not meet the criteria in C.1. or C.2. 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 809. You will receive a complete program description, information on application procedures and application forms. Business management technical assistance may be obtained from 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, GA 30305, telephone (404) 842-6796 or internet: lgt1.cdc.gov.

Programmatic technical assistance may be obtained from Tom Voglesonger, Program Manager, Injury Control Research Centers, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, MS-K58, Atlanta, GA 30341-3724, telephone (770) 488-4265 or internet address: tdv1.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 (even at the request of the applicant).

Please refer to Announcement 809 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), referenced in the Introduction, through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: August 22, 1997.

Joseph R. Carter,

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

[FR Doc. 97-22900 Filed 8-27-97; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Intent To Reallot Part C—Protection and Advocacy Funds to States for Developmental Disabilities Expenditures

AGENCY: Administration on Developmental Disabilities, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of intent to reallot Fiscal Year 1997 Funds, pursuant to Section 125 and Section 142 of the Developmental Disabilities Assistance and Bill of Rights Act, as amended (Act).

SUMMARY: The Administration on Developmental Disabilities herein gives notice of intent to reallot funds which were set aside in accordance with Section 142(c)(5) of the Act. Of the \$806,682 which was set aside for technical assistance and Indian Consortiums, \$534,360 was utilized for technical assistance and \$136,161 was awarded to an Indian Consortium. Therefore, the balance of \$136,161 has been released for reallotment.

Any State or Territory which wishes to release funds or cannot use the additional funds under Part C—Protection and Advocacy program for Fiscal Year 1997 should notify Joseph Lonergan, Director, Division of Formula, Entitlement and Block Grants, Office of Management Services, Office of Program Support, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, in writing within thirty (30) days of the date of this promulgation. Reallotment awards are anticipated to