Agency for Toxic Substances and Disease Registry

Workshop on the Psychological Effects of Hazardous Substances: Meeting

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the following meeting.

Name: Workshop on the Psychological Effects of Hazardous Substances.

Times and Dates: 7:30 a.m.–8:30 a.m., Registration; 8:30 a.m.–6:30 p.m., September 12, 1995; 8:30 a.m.–4 p.m., September 13, 1995.

Place: Gwinnett Civic and Cultural Center, 6400 Sugarloaf Parkway, Duluth, Georgia 30155, telephone 404/623–4966, FAX 404/623–4808.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 250 people. Advanced registration is encouraged. Please call the contact person listed below.

Matters To Be Considered and Purpose: Participants will be divided into the following three workgroups:

Workgroup 1: Neurobiology
Workgroup 2: Psychosocial Effects
Workgroup 3: Clinical Public Health Interventions

Invited experts will provide ATSDR with individual input and opinion regarding available information on the psychological effects of exposure to hazardous substances.

ATSDR will (1) compile a summary of this information in a monograph and (2) use the findings from this workshop to develop public health interventions.

Contact Person for More Information: Linda Champaign, Visions USA, Healey Building, 57 Forsyth Street, NW., Suite 1000, Atlanta, Georgia 30303, telephone 404/880–0006, extension 227.

Dated: August 23, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–21373 Filed 8–28–95; 8:45 am]

BILLING CODE 4163–70–M

Centers for Disease Control and Prevention

[Announcement 605]

Grants for Injury Control Research Centers Notice of Availability Of Funds for Fiscal Year 1996

Introduction

The Centers for Disease Control and Prevention (CDC) announces that grant applications are being accepted for Injury Control Research Centers (ICRC's). The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a PHS-led 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. For ordering a copy of ''Healthy People 2000,'' see the Section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**

Authority

This program is authorized under Sections 301 and 391–394A of the Public Health Service Act (42 U.S.C. 241 and 280b-280b-3). Program regulations are set forth in 42 CFR, Part 52.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke- free workplace and to promote the nonuse 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, 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. Current recipients of CDC injury control research center grants and injury control research program project grants are eligible to apply for continued support.

Availability of Funds

Approximately $2,250,000 is expected to be available in fiscal year (FY) 1996 to fund approximately three new or re-competing center awards. Should additional funds become available, priority will be given to funding currently approved/unfunded work at existing ICRCs. New awards can be made for a project period not to exceed three years, and re-competing continuation awards can be made for a project period not to exceed five years. The amount of funding available may vary and is subject to change. Beginning award dates for each submission are shown in the ''Receipt and Review Schedule'' section of this announcement. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

New center grant 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 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 ICRC's will be determined as follows:

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

Subject to program needs and the availability of funds, 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 phases may be made for up to $250,000 per year.

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.* Information on these reports may be obtained from the individuals listed in the section **WHERE TO OBTAIN ADDITIONAL INFORMATION;**

B. To support ICRC's 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 ICRC's 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.

Award Considerations

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 ICRC's 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 ICRC's. 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 ICRC's 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.

Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the previous heading **AWARD CONSIDERATIONS.** (A listing of where these requirements are described and/or documented in the application will facilitate the review process.) 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 by reviewers from the IGRC to determine if the application is of sufficient technical and scientific merit to warrant further review; 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. The primary review will be a peer evaluation (IRGRC) of the scientific and technical merit of the application. The final review will be conducted by the CDC Advisory Committee for Injury Prevention and Control (ACIPC), which will consider the results of the peer review together with program need and relevance. Funding decisions will be made by the Director, National Center for Injury Prevention and Control (NCIPC), based on merit and priority score ranking by the IRGRC, program review by the ACIPC, and the availability of funds.

A. Review by the Injury Research Grants Review Committee (IRGRC)

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. Site visits will be a part of this process for recompeting ICRC's. Reverse site visits may be a part of this process for new applicants.

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. Progress made as detailed in the application if the applicant is submitting a competitive renewal

application. Documented success examples 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 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. Within budgetary considerations, the ACIPC will establish annual funding levels as detailed under the heading, **AVAILABILITY OF FUNDS.**

C. Applications for Supplemental Funding

Supplemental grant awards may be made when funds are available 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.

Award Priorities

Special consideration will be given to re-competing Injury Control Research Centers.

Executive Order 12372 Review

Applications are not subject to the review requirements of Executive Order 12372, entitled Inter-Governmental Review of Federal Programs.

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.

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 to the Grants Management Specialist (whose address is given in this section Item B). It should be postmarked no later than one month prior to the submission deadline (September 30, 1995, for October 30, 1995, submission deadline). The letter should identify the relevant announcement number for the response, indicate the submission deadline which will be met, 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 Form PHS–398 (OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for PHS–398 contained in the Grant Application Kit. The narrative section for *each* project within an ICRC should not exceed 25 typewritten pages. Refer to section 4, page 10, of PHS–398 instructions for font type and size. *Applications not adhering to these specifications may be returned to applicant.* Applicants should submit an original and five copies to Maggie Slay, 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, MS E–13, 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. Supplemental materials received later than thirty days after the application receipt date are considered late and will be returned to the applicant.

D. Receipt and Review Schedule

This is a continuous announcement. Consequently, these receipt dates will be ongoing until further notice. The proposed timetables for receiving applications and awarding grants are as follows:

Receipt of new/revised/supplementary/competitive renewal applications	Initial review	Secondary review	Earliest award date
October 30, 1995.	January .	March	September 1, 1996.

Future receipt dates are as follows:

Receipt of new/revised/ supplementary/ competitive renewal applications	Initial review	Secondary review	Earliest award date
October .	January .	March	September.

Where to Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement Number 605. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from Maggie Slay, Grants Management Specialist, Grants Management Branch, Centers For Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS-E13, Atlanta, GA 30305, telephone (404) 842–6797. 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 (404) 488–4265.

Please refer to Announcement 605 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 Introducton, through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: August 23, 1995.

Joseph R. Carter,

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

[FR Doc. 95–21376 Filed 8–28–95; 8:45 am]

BILLING CODE 4163–18–P

Technical Advisory Committee for Diabetes Translation and Community Control Programs; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Technical Advisory Committee for Diabetes Translation and Community Control Programs.

Time and Date: 8 a.m.–4 p.m., September 19, 1995.

Place: Sheraton Gateway Hotel, Atlanta Airport, 1900 Sullivan Road, College Park, Georgia 30337, telephone 404/997-1100.

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with advising the Director, CDC, regarding priorities and feasible goals for translation activities and community control programs designed to reduce risk factors, morbidity, and mortality from diabetes and its complications. The Committee advises regarding policies, strategies, goals and objectives, and priorities; identifies research advances and technologies ready for translation into widespread community practice; recommends public health strategies to be implemented through community interventions; advises on operational research and outcome evaluation methodologies; identifies research issues for further clinical investigation; and advises regarding the coordination of programs with Federal, voluntary, and private resources involved in the provision of services to people with diabetes.

Matters To Be Discussed: Committee members will discuss the status of the National Diabetes Education Program; CDC's role in the National Institutes of Health Diabetes Prevention Program II, a collaborative program on diabetes with Russia; priorities of CDC's Division of Diabetes Translation State Diabetes Control Programs; future priorities and projects of the Division; and goals and activities of the Technical Advisory Committee for Diabetes Translation and Community Control Programs.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Cheryl Shaw, Program Specialist, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway NE., M/S K–10, Atlanta, Georgia 30341–3724, telephone 770/488–5004.

Dated: August 23, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–21372 Filed 8–28–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0275]

Drug Export; Atenolol Bulk Drug Substance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that IPR Pharmaceuticals, Inc., a part of Zeneca Group PLC, has filed an application requesting approval for the export of the bulk drug substance Atenolol to France to produce various approved finished formulations containing Atenolol alone or in combination.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that IPR Pharmaceuticals, Inc., a part of Zeneca Group PLC, P.O. Box 1967, Carolina, PR 00984, has filed an application requesting approval for the export of the bulk drug substance Atenolol to France. Atenolol is a synthetic, beta-selective adrenoreceptor blocking agent used alone or in combination with other antihypertensive agents. The firm has several approved applications using Atenolol from an approved bulk source for various finished dosage forms. The bulk drug substance Atenolol which is the subject of this notice will be manufactured in a new facility. The application was received and filed in the Center for Drug Evaluation and