Frequency: Annually.

Respondents: State Agencies on Aging.

Estimated Number of Responses: 52.

Total Estimated Burden Hours: 9,000.

Additional Information or Comments: The Administration on Aging is submitting to the Office of Management and Budget, for approval, an extension, with no revisions, of a reporting form and instructions for the State Annual Long-Term Care Ombudsman Report, pursuant to requirements in Section 712(b) and (h) of the Older Americans Act.

The form for which extension is requested was approved by the Office of Management and Budget, on an emergency basis, for use by the states in reporting on activities in FY 1997. It is the same form used by the states for their FY 1996 reports, except for minor changes made for the FY 1997 emergency request. These changes:

(1) modified the wording of some of the complaint categories to assist respondent in categorizing some complaints which had previously been placed under the ''other'' categories and

(2) Stipulated that several narrative responses which had not changed since the previous report do not need to be repeated.

The reporting form is for federal fiscal years 1998–2000. Written comments and recommendations for the proposed information collection should be sent within 30 days of the publication of this notice directly to the following address: Ms. Allison Herron Eydt, AoA Desk Officer, Office of Management and Budget, 1725 17th Street, N.W., Room 10235, Washington, D.C. 20503.

Dated: May 27, 1998.

Harry Posman,

Director, Executive Secretariat and Policy Coordination.

[FR Doc. 98–14477 Filed 6–1–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 98049]

National Institute for Occupational Safety and Health; Evaluation Of Toxicologic Risk Assessment Models Using Epidemiology Data Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC), the nation's prevention agency, announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program to evaluate the toxicologic risk assessment models using epidemiology data.

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 Occupational Safety and Health. (For ordering a copy of Healthy People 2000, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION**.)

CDC, NIOSH is committed to the program priorities developed by the National Occupational Research Agenda (NORA). For ordering a copy of the NORA, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION**.)

Authority

This program is authorized under Sections 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 [29 U.S.C. 669(a) and 671(e)(7)].

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and 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

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or woman-owned businesses are eligible to apply.

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

Availability of Funds

Approximately $106,000 is available in FY 1998 to fund one award. The award will be made for a 12-month budget period within a project period of up to three years. The amount of funding available may vary and is subject to change. The award is expected to begin on or about September 30, 1998. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Pub. L. 105–78) states in Section 503(a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Research on risk assessment methodology is one of the NORA priority areas. Quantitative risk assessment has become a requirement for the development of NIOSH recommended exposure limits and ultimately Occupational Safety and Health Administration and Mining Safety and Health Administration regulations. Animal bioassays have provided the scientific basis for most risk assessment models. The validity of

using animal bioassay data for predicting human risks has been increasingly under attack. Despite these concerns, toxicologic data is expected to remain a vitally important resource for risk assessment and risk management decisions. There is a clear need to gain a better understanding of when toxicologic data provide valid estimates of human risk and when they do not.

Epidemiologic studies that have information on exposures have been used by a few authors in an attempt to make comparisons with risk predictions from animal based models for cancer. However, these validation exercises have not been performed in a thorough and systematic fashion and questions have been raised about the appropriateness of the methods that have been used for these analyses. Furthermore, the evaluations that have been performed to date have been solely concerned with cancer and there has been virtually no research on the concordance between animal bioassay data and epidemiologic data for non-carcinogenic hazards. See the section **WHERE TO OBTAIN ADDITIONAL INFORMATION** for reference materials.

Purpose

The purpose of this program is to provide information on the validity and precision of risk estimates derived from risk assessment models based on toxicologic data for predicting human risk from occupational exposures in the workplace. This information will be useful to regulators and policy makers who frequently need to base decisions on setting safe levels of exposures in the workplace on animal bioassay data, since adequate human data is not available.

The major objective of this program is to develop and apply methods for evaluating the predictions from toxicologic risk assessment models for human risk using epidemiologic data. Some of the fundamental questions that may be addressed by this research would be:

- How good is the concordance between the risk predictions from exposure-response relationships observed in toxicologic and epidemiologic studies for cancer and non-cancer health effects?
- How does the degree of concordance vary for different cancer sites and non-carcinogenic health hazards?
- What factors influence the discordance between toxicologic and epidemiologic model predictions?
- Are the risk estimates developed from toxicologic models generally over or underestimates of the risk observed in epidemiologic studies?
- How may the pattern of exposures used in the toxicologic studies (lifetime) versus those experienced by workers in the epidemiologic studies (intermittent) influence the risk comparisons?
- Are there ways of adjusting the predictions from toxicologic models to more accurately predict human risks?

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for activities under A. (Recipient Activities), and CDC/NIOSH will be responsible for the activities listed under B. (CDC/NIOSH Activities).

A. Recipient Activities

The recipient will have primary responsibility for:

1. The identification of appropriate data resources,
2. Design of the study,
3. Management of the data,
4. Statistical analysis of the data, and
5. Prepare a report summarizing the study methodology, results obtained, and conclusions reached. Develop recommendations. Report study results to the scientific community.

B. CDC/NIOSH Activities

1. Provide scientific and technical collaboration for the successful completion of this project.
2. Identify linkages with researchers and public and private sector agencies and organizations to provide data.
3. Collaborate with the recipient in safety and health communication and dissemination efforts of prevention information.
4. Cooperate in preparation and publication of the written reports.

Technical Reporting Requirements

An original and two copies of annual progress reports are required. Timelines for the annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Annual progress report should include:

A. A brief program description.

B. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.

C. If established goals and objectives to be accomplished were delayed, describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

D. Other pertinent information, including the status of completeness, timeliness and quality of data.

Application Content

The entire application, including appendices, should not exceed 40 pages and the Proposal Narrative section contained therein should not exceed 25 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8½″ by 11″ paper, with at least 1″ margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets.

A. Title Page

The heading should include the title of grant program, project title, organization, name and address, project director's name, address and telephone number.

B. Abstract

A one page, singled-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract should include a work plan identifying activities to be developed, activities to be completed, and a time-line for completion of these activities.

C. Proposal Narrative

The narrative of each application must:

1. Briefly state the applicant's understanding of the need or problem to be addressed, the purpose, and goals over the *3* year period of this project.

2. Describe in detail the objectives and the methods to be used to achieve the objectives of the project. The objectives should be specific, time-phased, measurable, and achievable during each budget period. The objectives should directly relate to the program goals. Identify the steps to be taken in planning and implementing the objectives and the responsibilities of the applicant for carrying out the steps.

3. Provide the name, qualifications, and proposed time allocation of the Project Director who will be responsible for administering the project. Describe

staff, experience, facilities, equipment available for performance of this project, and other resources that define the applicant's capacity or potential to accomplish the requirements stated above. List the names (if known), qualifications, and time allocations of the existing professional staff to be assigned to (or recruited for) this project, the support staff available for performance of this project, and the available facilities including space.

4. Document the applicant's expertise, and extent of involvement in the areas of risk assessment, epidemiology and toxicology.

5. Provide letters of support or other documentation demonstrating collaboration of the applicant's ability to work with diverse groups, establish linkages, and facilitate awareness information.

D. Budget

Provide a detailed budget which indicates anticipated costs for personnel, equipment, travel, communications, supplies, postage, and the sources of funds to meet these needs. The applicant should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; describe the services to be performed; and provide an itemized breakdown and justification for the estimated costs of the contract; the kinds of organizations or parties to be selected; the period of performance; and the method of selection. Do not put these pages in the body of the application. CDC may not approve or fund all proposed activities.

Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

A. Understanding of the Problem (20%)

Responsiveness including: (a) applicant's understanding of the objectives; and (b) evidence of ability to design an effective evaluation study.

B. Experience (20%)

The extent to which the applicant's prior work and experience in risk assessment, epidemiology and toxicology issues is documented. Actual experience in evaluating toxicologic risk assessment models using epidemiologic data would be extremely helpful.

C. Goals, Objectives and Methods (25%)

The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable. The extent to which the methods are sufficiently detailed to allow assessment of whether the objectives can be achieved for the budget period. Clearly state the evaluation method for evaluating the accomplishments. The extent to which a qualified plan is proposed that will help achieve the goals stated in the proposal.

D. Facilities and Resources (10%)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

E. Project Management and Staffing Plan (15%)

The extent to which the management staff and their working partners are clearly described, appropriately assigned, and have pertinent skills and experiences. The extent to which the applicant proposes to involve appropriate personnel who have the needed qualifications to implement the proposed plan. The extent to which the applicant has the capacity to design, implement, and evaluate the proposed intervention program.

F. Collaboration (10%)

The extent to which all partners are clearly described and their qualifications and the extent to which their intentions to participate are explicitly stated. The extent to which the applicant provides proof of support (e.g., letters of support and/or memoranda of understanding) for proposed activities. Evidence or a statement should be provided that these funds do not duplicate already funded components of ongoing projects.

G. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should be sent to Victoria Sepe, 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, Room 321, Atlanta, GA 30305, no later than 60 days after the application deadline date. The Program Announcement Number 98049 and Program Title, Evaluation of Toxicologic Risk Assessment Models Using Epidemiology Data, should be referenced on the document. The granting agency does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date.

Public Health System Reporting Requirements

The applicant is not subject to review under the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.262.

Other Requirements

Paperwork Reduction Act

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

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to Victoria F. Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, CDC at the address listed in this section. It should be postmarked no later than June 17, 1998. The letter should identify program announcement number 98049, and name of the principal investigator. 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. Application

The original and five copies of the application PHS Form 398 (Revised 5/95, OMB Number 0925–0001) must be submitted to Victoria Sepe, 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, on or before July 15, 1998.

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

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

Where to Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to NIOSH Announcement 98049. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to NIOSH announcement 98049 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Leslie Stayner, Education and Information Division, National Institute for Occupational Safety and Health, Center for Disease Control and Prevention (CDC), 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 533–8365, or Internet address: lts2@cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

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

NORA

The National Occupational Research Agenda: copies of this publication may be obtained from The National Institute of Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226–1998 or phone 1–800–356–4674, and is available through the NIOSH homepage, ''http:/www.cdc.gov/niosh/nora.html''.

Reference Materials

Allen BC, Crump KS and Shipp AM (1988). Correlation between carcinogenic potency of chemicals in animals and humans. Risk Analysis 8(4): 531–557.

Ames B.N. and Gold L.S. (1990). Chemical carcinogenesis: Too many rodent carcinogens. Proc. Natl. Acad. Sci. 87;7772–7776.

Goodman G, and Wilson R. (1991). Quantitative predictions of human cancer risk from rodent carcinogenic potencies: A closer look at the epidemiological evidence for some chemicals not definitively carcinogenic in humans. Reg Tox and Pharm, 14;118–146.

Stayner LT and Bailer AJ (1993). Comparing toxicologic and epidemiologic studies: Methylene chloride—A case study. Risk Analysis, 13(6); 667–673.

Zeiss L. In Chemical Risk Assessment and Occupational Health (1994). Current Applications, Limitations and Future Prospects. CM Smith, DC Christiani and KT Kelsey eds. Auburn House, Westport, Conn.

Dated: May 26, 1998.

Diane D. Porter,

Acting Director, National Institute For Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–14464 Filed 6–1–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Good Clinical Practices In Investigational Product Research Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) (Office of Regulatory Affairs, New Orleans District Office) is announcing the following meeting: ''Good Clinical Practices In Investigational Product Research.'' The topics to be discussed are FDA regulatory requirements for the conduct of investigational product research and practical issues, such as, how to prepare for a data audit, what to expect during an investigation, and how to get current information from FDA. The purpose of this meeting is to promote and encourage open dialogue between FDA and professionals involved in investigational product research: Physicians, researchers, research coordinators, nurses, allied health professionals, and any other interested parties.

Date and Time: The meeting will be held on Friday, July 17, 1998; registration from 7:45 a.m. to 8:30 a.m.; meeting from 8:30 a.m. to 5 p.m.

Location: The meeting will be held at the Louisiana State University Medical Center, Medical Education Bldg., Lecture Room A, 1901 Perdido, New Orleans, LA 70112.

Contact: Rebecca A. Asente, Food and Drug Administration, New Orleans District Office (HFR–SE440), 4298 Elysian Fields Ave., New Orleans, LA 70122, 504–589–6344, ext. 158, FAX 504–589–6360.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, July 10, 1998. There is no registration fee for this meeting. Attendance will be limited to the first 200 applicants, therefore, interested parties are encouraged to register early. Priority will be given to those individuals located in Louisiana and Mississippi. Individuals located outside these States may register to attend the meeting and will be accepted if space is available.

If you need special accommodations due to a disability, please contact Rebecca A. Asente at least 7 days in advance.

Dated: May 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14463 Filed 6–1–98; 8:45 am]

BILLING CODE 4160–01–F