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*Acting Director, Office of Program Planning and Evaluation, Centers for Disease Control Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

**[Program Announcement 03049]**

## Research on the Impact of Law on Public Health; Notice of Availability of Funds

### A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 1704 of the Public Health Service Act, 42 U.S.C. 300u–3, as amended. The Catalog of Federal Domestic Assistance number is 93.283.

### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a grant program for research to evaluate the impact of law on public health. This program addresses all the ''Healthy People 2010'' focus areas.

The purpose of the program is to stimulate research evaluating the implementation and impact of law on the prevention and control of death, disease, injury, and disability, on health promotion, on the conduct of public health services, and on the public health system and infrastructure. In this context, ''law'' means statutes, regulations and rules, contract specifications, licensing requirements, case law and other judicial rulings, and other legally enforceable policies of the federal government, state governments and their political subdivisions, tribes, and territories.

Special emphasis will be given to research that will produce, on an accelerated basis, scientifically valid findings that can be used to improve law's contribution to public health preparedness for, and response to, terrorism, outbreaks of infectious disease, and other major public health threats and emergencies.

Measurable outcomes of the program will be in alignment with the following performance goal for the CDC Public Health Practice Program Office (PHPPO): Prepare state and local health systems, departments and laboratories to respond to current and emerging public health threats.

### C. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, technical schools, research institutions, public health and healthcare organizations, community-based organizations, faith-based organizations, and other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

**Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

Applications that are incomplete or non-responsive to the below requirements will be returned to the applicant without further consideration. The following are applicant requirements:

1. A principal investigator who has conducted scientific research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

2. Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing research evaluating public health law or other public policies, programs or interventions.

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

4. The overall match between the applicant's proposed research objectives and those described under the heading ''Program Requirements.''

### D. Funding

*Availability of Funds*

Approximately $500,000 is available in FY 2003 to fund approximately three awards. It is expected that the average award will be $165,000, ranging from $150,000 to $250,000. It is expected that the awards will begin on or about September 1, 2003, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

*Recipient Financial Participation*

Matching funds are not required for this program.

### E. Program Requirements

Research applications are solicited that address the specific program areas of interest below (not listed in priority order), and other areas the applicant demonstrates are significant for improved public health.

1. Terrorism: The impact of laws on public health preparedness for, and response to terrorism.

2. Infectious Diseases: The impact of laws on the prevention and transmission of diseases not related to terrorism, on the prevention of drug-resistant disease, and on patient safety.

3. Public Health Reporting: The effectiveness of state and local laws regarding the reporting of disease, injury, disability, and risk factors associated with those conditions.

4. Child, Adolescent, and Adult Health:

a. The impact of the absence of school-entry immunization laws on immunization levels.

b. The impact of legislatively mandated immunization insurance benefits (*e.g.*, first-dollar coverage laws) and of their enforcement on immunization levels.

c. The impact of standing orders laws on adult immunization levels.

d. The impact of state laws and case law on adolescent access to health care services and participation in research.

e. The impact of alcohol taxes on adolescent alcohol use and alcohol-related conditions.

5. HIV, STDs, and Tuberculosis: The impact of laws on the occurrence and transmission of HIV, sexually transmitted diseases, and tuberculosis, and the impact of laws on implementation of rapid HIV testing.

6. Injury: The impact of legislative and regulatory interventions on injury, and the impact of differing levels of their enforcement on injury.

7. The Built Environment and Public Health: The impact of State and local laws on the impact the Built Environment has on the health of the public.

8. Chronic Diseases:

a. The impact of State and local laws on chronic diseases and on risk factors for chronic diseases, with special

emphasis on diabetes, obesity, tobacco, physical activity, and nutrition.

b. The impact of state and local laws on utilization of cancer screening services, on cancer incidence and mortality reporting, and on the variability of state coverage for Medicaid cancer services (including screening, diagnosis, treatment, and post-treatment services).

c. The impact of State and local laws on the occurrence of environmental health hazards (*e.g.*, mold and poor indoor air quality) in schools and on subsequent health and learning effects on students.

d. The impact of laws on self-administration of prescribed medications for students and on subsequent health and learning effects on students.

e. The impact of laws on the location of schools (*e.g.*, in proximity to hazardous waste sites) and on subsequent health and learning effects on students.

9. Occupational Health: The impact of Federal and State regulations, municipal ordinances, contract specifications, and health-related litigation on the safety and health of workers.

10. Public Health System: The impact of laws on the public health system and infrastructure and on the capacity of the public health workforce, health departments and laboratories, and private entities to perform essential public health services.

11. Public Health Practice:

a. The impact on public health practice of the ''Standards for Privacy of Individually Identifiable Health Information'' (the Privacy Rule) of the Health Insurance Portability and Accountability Act.

b. The impact of privacy laws on establishment and use of electronic medical records, in general, and on immunization and other public health registries, in particular.

For all these programmatic areas, it is the intent of this program to fund applications comprising innovative, multi-disciplinary research strategies. Model approaches also are sought for evaluating the impact of public health laws, within or across different areas of public health (*e.g.*, infectious diseases, chronic diseases, environmental health, injury prevention, and public health systems and infrastructure).

As appropriate and feasible, applicants are encouraged to address the fullest complement of possible measures for assessing outcomes. These measures could include health and safety outcomes (*e.g.*, frequency and severity of injury, illness, disability, or hazard exposure; frequency of risk or of preventive behaviors; economic outcomes (*e.g.*, costs at the level of the individual, household, community, industry, or society; or distribution of costs among payers); social outcomes (*e.g.*, impact on educational attainment, employment); as well as measures of change in behavior, knowledge, attitudes, use of technological interventions, the capacity of public health systems infrastructure, the quality and quantity of prevention services and public health practice, and other measures.

Applications are encouraged which include plans to obtain and analyze information on the implementation of the referenced laws, as appropriate and necessary for evaluating their impact, including quantitative and qualitative information on application, enforcement, or compliance activities associated with a law under evaluation, and on compliance-related knowledge, attitudes, and behaviors of the target audience(s). Information on implementation also may address factors that may either impede or promote the contribution laws make to public health.

**F. Content**

**Letter of Intent (LOI)**

An LOI is required for this program. LOIs will be evaluated to determine which applicants will be invited to submit a full application based on the reviewer's evaluation of the LOI, as described in Evaluation Criteria. LOIs must be no more than four pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

Mandatory Identifying Information

The following identifying information must appear only on the first page of the LOI:

1. The Program Announcement and number.

2. The name, address, telephone number, and fax number of the applicant and the e-mail address of a contact person.

3. The names, degrees, and titles of the principal investigator and all key project personnel.

This identifying information must not appear on the second, third or the fourth page.

Mandatory Project Information

The following information on the proposed research project must appear on the second, third and fourth pages:

1. A narrative description of the proposed research plan.

2. The number of months or years the project will take to completion.

3. The total funding required for each year of the project.

LOIs that do not include the mandatory information will be deemed non-responsive; the applicants will not be invited to submit full applications.

**Applications**

The Program Announcement title and number must appear in the application. Use the information in the Programmatic Interest Areas, Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your PHS 398 (OMB Number 0925–0001) application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 pages, single-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of, at a minimum, a plan, objectives, methods, evaluation and budget. Applications for research on the impact of public health laws should include the following information:

1. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to improving law's contribution to public health.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.

4. A description of the role and responsibilities of the principal investigator.

5. A description of all the project staff and their role in the proposed research, regardless of their funding source, including their title, qualifications, experience, percentage of time each will devote to the project, as well as the portion of their salary to be paid by the grant.

6. A description of those activities related to, but not supported by the grant.

7. A description of the involvement of other entities that will relate to the proposed research, if applicable, including a letter of commitment from each and a clear statement of their role.

8. A detailed first year's budget for the grant with future annual projections, if relevant, including direct and indirect costs.

**G. Submission and Deadline**

*Letter of Intent (LOI) Submission*

The LOI must be received by 4 p.m. Eastern Time May 9, 2003. Submit the LOI to: Technical Information Management—PA#03049, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341–4146.

LOIs may not be submitted electronically.

*Application Forms*

Submit the original and two copies of PHS 398 (OMB Number 0925–0001) (Errata Instruction Sheet for PHS 398 is posted on the CDC Web site.) Forms are available at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.* If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

*Submission Date, Time, and Address*

The application must be received by 4 p.m. Eastern Time, July 9, 2003.

Submit the application to: Technical Information Management—PA#03049, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

*CDC Acknowledgement of Application Receipt*

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

*Deadline*

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to 1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or 2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications that do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

**H. Evaluation Criteria**

*Letter of Intent*

The Letter of Intent (LOI) will be reviewed by a panel to include reviewers other than CDC staff from the funding Centers/Institutes/Offices, and who will be involved in the peer review panel for the applications. The panel will review the LOI to determine if it indicates research of sufficient relevance to CDC program priorities and potential scientific significance to warrant submission of a full application. Only principal investigators whose LOIs are determined to meet these criteria will be requested to submit full applications. Evaluation criteria to be applied include the following:

1. Relevance to CDC program priorities; (60 percent)
2. Potential Scientific Significance. (40 percent)

*Application*

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goal stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and will be an element of evaluation.

Applications will be reviewed for completeness and responsiveness as outlined under the ''Eligible Applicants'' Section (Items one through four.) Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is especially important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

Applications which are complete and responsive may be subjected to a preliminary evaluation procedure by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review; 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 peer review group.

Criteria to be considered in the review are listed below.

All criteria are of equal importance, however, an application does not need to be strong in all categories to be judged likely to have a major scientific impact.

1. Significance—Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of this study on the concepts or methods that drive this field?

2. Approach—Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

3. Innovation—Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies?

4. Investigator—Is the principal investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other significant investigator participants?

5. Environment—Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

6. Human Subjects—Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? An application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

7. Dissemination—What plans have been articulated for disseminating findings?

A second programmatic review will be conducted by a panel of Senior Federal Officials. The Officials will review the ranked proposals to assure maximal impact and balance of the proposed research. The factors to be considered will include:

1. The results of the peer review.

2. The importance of the proposed research for meeting the primary goals of this initiative, as described in ''Program Requirements'' section.

3. Budgetary considerations.

**I. Other Requirements**

*Technical Reporting Requirements*

Provide CDC with the original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities and Objectives.

b. Current Budget Period Financial Status.

c. New Budget Period Proposed Activities and Objectives.

d. Detailed Line-Item Budget and Justification for the new budget period.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

*Additional Requirements*

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of this announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–7 Executive Order 12372 Review

AR–8 Public Health System Reporting Requirements

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR–15 Proof of Non-Profit Status (if applicable)

**J. Where To Obtain Additional Information**

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—*http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

Business management technical assistance may be obtained from: Merlin J. Williams, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2765, E-mail address: *MWilliams2@cdc.gov*.

For program technical assistance, contact: Anthony D. Moulton, PhD, Public Health Law Program, Public Health Program Practice Office, Centers for Disease Control and Prevention, 4770 Buford Hwy. (K–36), Atlanta, Georgia 30341–3724, Phone: 770–488–2405/Fax 770–488–2474, E-mail: *ADM6@CDC.GOV*.

Dated: April 11, 2003.

**Sandra R. Manning,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Council for the Elimination of Tuberculosis: 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 council meeting.

*Name:* Advisory Council for the Elimination of Tuberculosis (ACET).

*Times and Dates:* 8:30 a.m.–5 p.m., June 4, 2003; 8:30 a.m.–12 p.m., June 5, 2003.

*Place:* Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333. Telephone (404) 639–8008.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating TB.

*Matters to be Discussed:* Agenda items include issues pertaining to improving TB control efforts in the Southeast, TB among the foreign born, and other TB-related topics.

Agenda items are subject to change as priorities dictate.

**FOR FURTHER INFORMATION CONTACT:** Paulette Ford-Knights, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 11, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0454]**

### Agency Information Collection Activities; Announcement of OMB Approval; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Notice of a Claim for Generally Recognized as Safe Exemption Based on