

Respondents	No. of responses	No. of responses/re-spondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Induction .....	40	1	1.5	60
Out-of-scope Verification .....	140	1	0.066	9
Sample Listing Sheet:				
ASC Personnel .....	224	12	0.5	1,344
Census Personnel .....	267	12	0	0
Medical Abstract:				
ASC Personnel .....	324	250	0.2	16,200
Census Personnel .....	167	250	0.03333	1,392
Annual Update .....	491	1	0.083	41
Quality Control .....	245	200	.0333	163
Total .....				19,209

Dated: April 24, 1996.

Wilma G. Johnson,

*Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

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#### **National Center for Health Statistics; ICD-9-CM E Code Revisions**

**AGENCY:** National Center for Health Statistics, Centers for Disease Control and Prevention (CDC), DHHS.

**ACTION:** Notice.

**SUMMARY:** The National Center for Health Statistics has approved the following expansion to the External Cause Codes in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). These ICD-9-CM E-Code revisions will become effective October 1, 1996. The official guidelines for the application of E-codes for morbidity purposes will also be updated at that time. The official government version of the ICD-9-CM which will include all the revisions effective October 1, 1996, will be found on the ICD-9-CM CD-ROM which will be available through the Government Printing Office.

#### **E967 Child and adult battering and other maltreatment**

- E967.0 By father or stepfather
- E967.2 By mother or stepmother
- E967.3 By spouse or partner
- E967.4 By child
- E967.5 By sibling
- E967.6 By grandparent
- E967.7 By other relative
- E967.8 By non-related caregiver

**FOR FURTHER INFORMATION CONTACT:** Donna Pickett, R.R.A., Co-chair, ICD-9-CM Coordination and Maintenance Committee, National Center for Health Statistics, CDC, telephone (301) 436-7050.

Dated: April 24, 1996.

Joseph R. Carter,

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

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#### **[Announcement 619]**

#### **HIV-Related Tuberculosis Preventive Therapy Regimen Demonstration Cooperative Agreements**

##### **Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds to continue the cooperative agreement program started in FY 1992 through announcement number 261 entitled "Human Immunodeficiency Virus (HIV) Related Tuberculosis (TB) Preventive Therapy Regimen (PTR) Demonstration Cooperative Agreements." Current recipients will compete to extend the project period for an additional three years to allow sufficient time to actively monitor and ensure compliance with drug therapy, assess toxicity, and appropriately evaluate patients for up to two years after completion of preventive therapy. All applicants, however, who meet the eligibility criteria will be considered. See the section entitled *Eligible Applicants*.

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 HIV Infection and Immunization and Infectious Diseases. (For ordering a copy of "Healthy People 2000," see the section *Where To Obtain Additional Information*.)

##### **Authority**

This program is authorized under Section 317E of the Public Health Service Act, [42 U.S.C. 247b-6], as amended.

##### **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 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**

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, and colleges; and research institutions, hospitals, other public and private organizations, State and local governments or their bonafide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply. Applicants must have the ability to (1) identify, obtain informed consent, and enroll a minimum of 25 dually-infected (TB/HIV-infected) persons and start them on one of two TB preventive regimens according to the randomization schedule provided by CDC and (2) conduct patient follow-up according to accepted clinical study practices. A copy of the prescribed regimens is included in the application kit. Applicants must be able to complete all phases of the project within the proposed three year project period.

Preference will be given to competing continuation applications submitted by the current cooperative agreement recipients funded in FY 1992 through competitive announcement number 261 entitled "Human Immunodeficiency

Virus (HIV)-Related Tuberculosis (TB) Preventive Therapy Regimen (PTR) Demonstration Cooperative Agreements." Current recipients are: Beth Israel Medical Center, Cathedral Healthcare System, Inc., City of Chicago, Johns Hopkins University (Brazil), Johns Hopkins University (Haiti), Trustees of Health and Hospitals of Boston, and the University of New Jersey.

#### Availability of Funds

Approximately \$2,000,000 is available in FY 1996 to fund up to seven awards. It is expected that the average award will be \$285,000, ranging from \$232,000 to \$508,000. Awards are expected to begin on or about September 30, 1996, for a 12-month budget period within a three-year project period. 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.

#### Purpose

The purpose of this program is to improve preventive treatment regimens for HIV-related TB through applied research. Applied research, as used in the context of this announcement, means the process of the development and evaluation of practical operational approaches and solutions to HIV-related TB problems and the evaluation of new technology (e.g., new drugs, new drug regimens, new methods of testing drug effectiveness, and applicability.)

Specific objectives of this project are to:

A. Determine the efficacy of a rifampin/pyrazinamide drug regimen (as prescribed by CDC) in preventing the development of TB in HIV-infected persons at risk of developing TB.

B. Describe the host factors that affect the efficacy of TB preventive therapy.

C. Evaluate the toxicity and acceptability of the drug regimen in the prevention of TB.

#### Program Requirements

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

##### A. Recipient Activities

1. Develop and implement strategies that are applicable to TB/HIV-infected persons in the United States including: (a) methods and strategies to successfully identify, enroll, and administer appropriate preventive drug

therapy to HIV-infected persons co-infected with *M. tuberculosis*; and (b) methods to actively monitor and ensure compliance with drug therapy, assess toxicity, and appropriately evaluate patients for up to two years after completion of preventive therapy.

2. Identify and enroll a minimum of 25 dually-infected (TB/HIV-infected) persons into one of two prescribed preventive therapy regimens. (A copy of the prescribed regimen is included in the application kit.)

3. Implement specified follow-up procedures to monitor toxicity and efficacy in dually-infected persons receiving the prescribed preventive therapy.

4. Develop and implement an evaluation plan that measures the effectiveness of the trial regimen employed.

5. Compile and disseminate findings.

##### B. CDC Activities

1. Provide consultation and technical assistance in planning, developing, implementing, and evaluating strategies.

2. Provide up-to-date scientific information and coordinate the exchange of information among recipients.

3. Assist in data management, analysis, and the evaluation of programmatic activities.

4. Assist in the preparation and publication of findings.

##### Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria. (100 total points maximum)

1. The extent to which the applicant has demonstrated the ability to enroll at least 25 dually-infected (TB/HIV-infected) persons and start them on one of two TB preventive regimens according to the randomization schedule provided by CDC (a copy of the prescribed regimens is included in the application kit). In addition, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. Specifically, the following items will be addressed:

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

b. The appropriateness of the proposed justification when representation is limited or absent.

c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants

include establishing partnerships with community(ies) and recognition of mutual benefits. (60 points)

2. The ability of the applicant to perform active follow-up procedures on all participants who receive preventive therapy (defined as persons who are currently receiving drugs or those who have completed the drug therapy portion of their treatment) including methods to deal with noncompliant patients; and the extent to which qualified and experienced personnel are available to carry out the proposed follow-up activities. (20 points)

3. The adequacy of the proposed plans to evaluate progress in implementing methods and achieving objectives. (20 points)

4. Other (Not Scored).

#### Budget

The budget must be reasonable, clearly justifiable, and consistent with the intended use of funds.

#### Human Subjects

Procedures adequate for the protection of human subjects must be documented: (1) protections appear adequate and no comments or concerns are raised, or (2) protections appear adequate, but comments are made regarding the protocol, or (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate resulting in unacceptability of the entire application.

#### Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

#### Public Health System Reporting Requirements

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

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance numbers are 93.947, Tuberculosis Demonstration, Research, Public and Professional Education; and 93.118, Acquired Immunodeficiency Syndrome (AIDS) activities.

#### Other Requirements

Confidentiality: Applicants must have in place systems to ensure the confidentiality of all patient records.

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. Assurances 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 form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of the IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

**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, Alaska 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. 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 (a copy is included in the application kit).

**Pre- and Post-test Counseling and Partner Notification:** Recipients are required to provide HIV antibody testing to determine a person's HIV infection status; therefore, they must comply with State laws and regulations and CDC guidelines regarding pre- and post-test counseling and partner notification of HIV-seropositive patients. A copy of the guidelines will be included in the application kit. Recipients must also comply with State and local health department requirements relating to specific reportable diseases or conditions. Recipients must provide referrals for HIV diagnosis and treatment.

**HIV/AIDS Requirements:** Recipients must comply with the document entitled "Content of AIDS-Related Written Materials, Pictorials,

Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions" (June 1992), a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program review panel such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department consistent with the Content guidelines. The names of the review panel members must be listed on the Assurance of Compliance form (CDC 0.1113), which is included in the application kit.

#### Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road NE., Room 300, Mailstop E-15, Atlanta, GA 30305, on or before July 1, 1996.

1. **Deadline:** Applications shall 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 committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

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

#### Where To Obtain Additional Information

Questions on application procedures and the application package, and business management technical assistance may be obtained from Manuel Lambrinos, 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, Mailstop E-15, Atlanta, GA 30305, telephone (404) 842-6777, or Internet address: MYL5@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Veronica Greene, D.D.S., M.P.H., Division of Tuberculosis Elimination, National Center for STD, HIV, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-10, Atlanta, GA 30333, telephone (404) 639-8123.

Please refer to Announcement Number 619 when requesting information or 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: April 24, 1996.

Joseph R. Carter,

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

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### The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention Announces the Following Meeting

**Name:** Scientific and Technical Discussion of the Draft Document, "Criteria for a Recommended Standard: Occupational Exposures to Metalworking Fluids (MWFs)."

**Times and Dates:** 9 a.m.-5:30 p.m., June 13, 1996. 9 a.m.-5:30 p.m., June 14, 1996.

**Place:** Drawbridge Inn, Yeomans Hall, I-75 and Buttermilk Pike, Fort Mitchell, Kentucky 41017.

**Status:** Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

**Purpose:** The purpose of this meeting is to discuss the scientific and technical content of the draft NIOSH document, "Criteria For a Recommended Standard: Occupational Exposures to Metalworking Fluids (MWFs)," prior to finalizing the criteria document for publication and transmittal to the Department of Labor. This review will focus on all aspects of the criteria document including: composition and formulation of MWFs, potential adverse health effects from exposure to MWFs, occupational exposure data, and the feasibility of controlling exposures to the NIOSH recommended exposure limit of 0.5 mg/m<sup>3</sup> (total particulate).

#### Contact Persons for More Information:

Technical information may be obtained from Brenda Boutin, NIOSH, CDC, 4676 Columbia Parkway, M/S C-32, Cincinnati, Ohio 45226, telephone 513/533-8345, e-mail address: hhal@NIOSDT1.em.cdc.gov.

Persons wishing to attend or make a presentation at the meeting, obtain a copy of