

Respondents	No. of re- spondents	No. of re- sponses/re- spondent	Avg. burden per response (in hours)	Total burden (in hours)
Nonresponse Studies .....	600	1	60/60	600
Total .....	.....	.....	.....	11,225

Dated: June 23, 2000.

**Nancy Cheal,**

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

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Centers for Disease Control and  
Prevention**

[30DAY-45-00]

**Agency Forms Undergoing Paperwork  
Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

**Proposed Projects**

1. Survey of Laboratory Practices for Nucleic Acid Amplification Tests for *Mycobacterium tuberculosis* (M.tb NAA)—New—As part of the continuing effort to support public health objectives of treatment, disease prevention and

surveillance programs, the Public Health Practice Program Office (PHPPPO), Centers for Disease Control and Prevention (CDC) seeks to collect information from both public health and private sector laboratories performing nucleic acid amplification tests for *Mycobacterium tuberculosis*. *Mycobacterium tuberculosis* (TB) infection has reemerged as a significant public health concern in the United States. Since TB is easily transmitted, early detection of infection is imperative for control and prevention. CDC guidelines have advocated the use of the acid-fast bacilli smear (AFB), followed by culture, to confirm a diagnosis of tuberculosis. However, research and development have led to the design and marketing of nucleic acid amplification-based methods for the rapid detection of *Mycobacterium tuberculosis* (M.tb) directly from clinical sputum specimens. Since the FDA approval of two commercial M.tb NAA, CDC has become keenly interested in the analytic accuracy and clinical utility of these tests, especially from the standpoint of early detection and control of tuberculosis.

Literature reports indicate variability in sensitivities, specificities, and predictive values for M.tb NAA, depending on the experimental design, the population being studied, and the test methodology. Overall, both sensitivity and specificity are reported to be relatively high compared with AFB smear and culture results. However, there are several important potential sources of error including contamination problems inherent to

nucleic acid technology, cross-contamination with other mycobacteria, sub-optimal laboratory practices, and unknown factors. The use of M.tb NAA tests for rapidly diagnosis may be useful for controlling TB, particularly in high prevalence populations. However, the clinical utility and efficacy of M.tb NAA tests remains in question. Because of the uncertainty surrounding the analytical accuracy and clinical validity of the tests, the potential sources of error, and the subsequent potential expense of incorrect treatment.

The goal of the proposed project is to collect laboratory practice data, in conjunction with performance data, through a survey administered to current participants in the CDC's M.tb NAA Performance Evaluation Program, to determine if laboratory practices are associated with the risk of errors in these tests. Information collected in the survey will be on test methods, quality assurance, quality control and reporting practices, and test utilization. The survey will also collect demographic information regarding the types of laboratories where testing is performed. CDC will use this data as a primary source of critical information to develop laboratory guidelines and recommendations for performance and utilization of M.tb NAA tests. The benefit of this data and the subsequent recommendations to public health will be the utilization of enhanced testing practices in the control and elimination of *M. tuberculosis* infection in the United States. The total annualized burden is estimated to be 55 hours.

Respondents	No. of re- spondents	No. of re- sponses/re- spondent	Avg. burden per response (in hours)	Total burden (in hours)
Laboratories .....	110	1	30/60	55
Total .....	.....	.....	.....	55

Dated: June 23, 2000.

**Nancy Cheal,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement Number 00064]

#### Notice of Availability of Funds; Announcement of a Cooperative Agreement With the Minority Health Professions Foundation To Enhance Professional Education, Research Infrastructure, and Community Service in the Areas of Health Promotion and Disease Prevention Partnering With African American Institutions

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the availability of fiscal year (FY) 2000 funds for a cooperative agreement program with the Minority Health Professions Foundation (MHPF). The purpose of the program is to assist the Minority Health Professions Foundation in the following manner:

1. To improve the practice of public health at member schools by strengthening their public health infrastructure;
2. To enhance the quantitative and qualitative analytic research infrastructure of the participating institutions;
3. To strengthen the educational and professional development of minority health professionals and educators;
4. To support student training initiatives, in order to introduce public health to minority students;
5. To provide health education and outreach for decreasing the needs of the poor, minority, and under-served populations; and
6. To enhance the interactions between the Minority Health Professions Foundation schools, the historically black colleges and universities and public health institutions.

This program addresses the commitments of the CDC and ATSDR in achieving the health promotion and disease prevention objectives of "Healthy People 2010", a national activity to reduce morbidity and mortality, while improving the quality of life. This announcement is related to

the 2010 objectives, which specify improving the health of groups of people bearing a disproportionate burden of poor health, as compared to the total population. The framework of "Healthy People 2010" consists of two broad goals which are to:

1. Increase quality and years of healthy life; and
2. Eliminate health disparities.

The goals of "Healthy People 2010" have been established as the Nation's prevention goals and as a scorecard for monitoring health status. The nations goals and objectives established in "Healthy People 2010" will build upon the foundation for establishing a small set of leading health indicators that could be presented to the general public and non-health professionals as an introduction to "Healthy People". "Healthy People 2010" will be a tool for monitoring America's health. For the conference copy of "Health People 2010" visit the internet site: <<http://www.health.gov/healthypeople>>.

Eliminating disparities by the year 2010 will require new knowledge about the determinants of disease and effective interventions for prevention and treatment. It will also require improved access for all to the resources that influence health. Reaching this goal will necessitate improved collection and use of standardized data to correctly identify all high-risk populations and monitor the effectiveness of health interventions targeting these groups. Research dedicated to a better understanding of the relationships between health status and income, education, race and ethnicity, cultural influences, environment, and access to quality medical services will help us acquire new insights into eliminating the disparities and developing new ways to apply our existing knowledge toward this goal. Improving access to quality health care and the delivery of preventive and treatment services will require working more closely with communities to identify culturally sensitive implementation strategies.

While the nation has made remarkable progress in understanding the causes and risks for developing diseases that have important implications for the health of all Americans, the health status of the nation's minority and poor lag considerably behind that of White Americans. The contributing factors for many disparities include inadequate family incomes, lack of access to medical care, and environmental hazards. The greatest opportunities for improvement and the greatest threats to the future health status of the Nation reside in the population groups that

have historically been disadvantaged economically, educationally and politically. In partnering with different racial and ethnic groups, the CDC can work closely with institutions, organizations, and communities to help eliminate disparities in health while meeting the goals of "Healthy People 2010".

##### B. Eligible Applicants

Assistance will be provided only to the Minority Health Professions Foundation (MHPF). No other applications are solicited.

The MHPF is the most appropriate and qualified organization to provide services specified under this cooperative agreement because:

1. The MHPF is dedicated to supporting the organizational growth of minority health professional schools to ensure the advancement of specific research in minority health, the education and professional development of minority health care professionals and educators, and the continuing provision of health services in minority and poor communities;

2. The MHPF represents twelve member institutions which include medical, dental, pharmacy, and veterinary medicine schools in historically African-American colleges and universities. Collectively, these institutions have trained one out of every two African American physicians, dentists, and pharmacists; and three out of every four African American veterinarians. The member institutions have also trained a substantial number of other minority and non-minority health professionals;

3. The MHPF member institutions are comprised of the Historically Black Colleges and Universities (HBCUs) that not only house the health professions schools, but three of which house schools of public health;

4. The primary objective of the MHPF and the nine Historically Black Colleges and Universities is to address the health needs of African American and other minority population groups;

5. The MHPF institutional members have significantly fostered and advanced dramatic growth and expansion of its member institution's collaborative efforts, bolstered and supported considerable increase in public health, medical and scientific research, and assisted in amplifying minority health community education and outreach nationally;

6. The MHPF and its member schools have the capacity to conduct basic sciences and clinical research, and are attacking the various diseases and conditions that disproportionately