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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Tuberculosis Elimination and Laboratory Cooperative Agreements

Program Announcement Type: New.

Program Announcement Number: 05003.

Catalog of Federal Domestic Assistance Number: 93.116.

Application Deadline: July 26, 2004.

I. Funding Opportunity Description

I.1. Authority

This program is authorized under section 317 E of the Public Health Service Act, (42 U.S.C. 247, b–6), as amended.

I.2. Purpose

A. TB Prevention and Control

The purpose of the Tuberculosis (TB) Elimination Cooperative Agreement Program is to assist the current efforts of State and local TB programs to prevent, control, and eventually eliminate TB in the United States. Financial assistance is provided to TB programs to ensure that program needs for the core TB prevention and control activities are met. This program addresses the ''Healthy People 2010'' focus area of Immunization and Infectious Diseases in conjunction with the Government Performance and Results Act of 1993 (GPRA).

Funds are available for recipients to address the core TB prevention and control activities (*i.e.*, completion of therapy, contact investigation, TB surveillance, TB public health laboratory, human resource development, and program evaluation).

Measurable outcomes of program progress will be in alignment with all of the following performance goal(s) for the National Center for HIV,STD, and TB Prevention (NCHSTP):

(1) Increase the percentage of TB patients who complete a course of curative TB treatment within 12 months of initiation of treatment (some patients require more than 12 months).

(2) Increase the percentage of TB patients with initial positive cultures who also are tested for and receive drug susceptibility results.

(3) Increase the percentage of infected contacts of infectious cases that are placed on treatment for latent TB infection (LTBI) and complete a treatment regimen.

(4) Increase the percentage of other high-risk infected persons who are placed on treatment for LTBI and complete a treatment regimen.

(5) Increase the percentage of immigrants and refugees designated as Class A, B1, or B2 who are appropriately evaluated and treated. Refer to the following Web link, pages 2–6, for classification descriptions. *http://www.cdc.gov/ncidod/dq/pdf/ds-forms-instructions.pdf*.

(6) For jurisdictions with greater than 50 reported cases of TB occurring annually in U.S.-born African Americans, decrease the case rate.

(7) Increase the proportion of adults with TB who have been tested for HIV.

The highest priority TB prevention and control activities are the following activities: Finding all cases of active TB and ensuring, through appropriate case management, completion of therapy; finding and evaluating persons who have had contact with infectious TB patients, identifying those with TB and LTBI, and completing treatment of TB disease and LTBI; conducting program evaluation; ensuring human resource development through internal project training and education; and conducting TB surveillance and TB public health laboratory activities that are essential to addressing these priorities. Each of these activities is essential to effective TB prevention and control, and they are mutually reinforcing. Thus, they constitute a ''package'' of core activities. These activities should be carried out by all TB prevention and control programs, taking precedence over lower priority activities. Lower priority activities are those such as targeted testing and treatment of LTBI in high risk populations.

State TB programs differ in the level of services and resources they provide to local programs and the amount of authority they have over local program activities. Regardless of these differences, state programs should work closely with their local TB programs to ensure that program activities are carried out appropriately and program objectives are met. States should provide leadership and technical assistance to the local programs in assessing program needs, setting local objectives, measuring performance, identifying problems, and designing interventions. In addition, State TB programs should facilitate resolution of inter-jurisdictional challenges (such as ensuring continuity of case management and treatment of persons with active TB who move between jurisdictions).

Directly funded cities should work closely with the state TB program to facilitate consistency on statewide issues, minimize duplication of efforts, and share all reports that are sent to Centers for Disease Control and Prevention (CDC) with the State TB program.

B. Regional TB Training and Medical Consultation Centers (RTMCCs)

Additional funds are available for the establishment of geographically distributed regional training and medical consultation centers.

The first major activity of the Regional TB Training and Medical Consultation Centers (RTMCC) is to increase human resource development for the prevention and control of TB through education and training activities. RTMCCs will serve as centers of excellence within their assigned regions by providing innovative and quality human resource approaches in two areas:

(1) Training courses and technical assistance to others developing and providing TB courses.

(2) Educational and training material product development.

Human resource development activities at RTMCCs should include:

- Developing and enhancing relationships with State and local public health agencies for TB control, as well as other partners (*see* below for a list of potential partners).
- Expanding capacities to provide professional education and training in tuberculosis to State and local health agencies and other partners.
- Working with State and local public health agencies to identify training needs of public health workers and private providers.
- Working with State and local public health agencies to assess and monitor specific training needs in TB.
- Developing competency-based education and training courses.
- Collaborating with State and local health agencies to develop methods for evaluating the effectiveness of the training activities.
- Identifying and sharing best practices, models, and innovative approaches to TB practices through the development of courses and materials.
- Assuring accountability through frequent monitoring and evaluation of RTMCC activities and materials.

The RTMCCs should work closely with local, State, and regional representatives from TB programs as

well as with other partners that include, but are not limited to, the following:

- Tuberculosis Education and Training Network (TB ETN) members.
- TB education and training focal points of other grantees funded under this announcement.
- Additional partners (should include, but are not limited to the following organizations, agencies and groups within the geographic catchment area: Health Resources and Services Administration (HRSA) primary care centers; AIDS education and training centers; STD training centers; private providers; medical, nursing, and public health schools and associations; regional TB controller associations; and TB advisory councils).

The second major activity of the RTMCCs is to increase the capacity for appropriate medical evaluation and management of persons with TB disease and infection in their assigned region. RTMCCs will:

- Develop and implement a medical consultation service for their assigned region.
- Develop and implement a plan to maintain and increase the capacity of the region to appropriately evaluate and medically manage persons with TB disease and infection.

C. TB Public Health Laboratory

Effective treatment and control of TB require that timely and reliable TB laboratory services be available to clinicians and TB controllers. Delays in the laboratory confirmation of TB and reporting of drug-susceptibility results lead to delays in initiation of therapy, prolonged infectiousness, inappropriate therapy, and missed opportunities to prevent transmission. As part of the Centers for Disease Control and Prevention's (CDC) response to the threat of multidrug-resistant tuberculosis (MDR–TB), (National Action Plan to Combat MDR–TB), cooperative agreement funds were provided to strengthen public health laboratories and an increased emphasis was placed on providing laboratory results in a timely manner. During the past decade, laboratories made tremendous strides in improving test performance. These improvements contributed to the resumption in the decline of the incidence of TB and the decrease in MDR–TB cases nationwide.

To reach the goal of eliminating TB in the U.S., the recent improvements in laboratory testing must be translated into improvements in TB treatment, prevention, and control. The critical next step will be to develop an integrated system that ensures timely laboratory testing and timely flow of information among laboratorians, clinicians, and TB controllers. Public health laboratories must take a leadership role to develop such a system and improve communication among laboratorians, clinicians, and TB controllers. Keys to providing timely, reliable laboratory services include (1) understanding the structure, performance, and cost of the current network of service providers and users, (2) developing a referral and information network to ensure reliable testing and the timely flow of specimens and information, and (3) using quality improvement principles to evaluate and improve the performance of the laboratory service network.

In recognition of this critical need, the primary purpose of the FY05–FY09 Laboratory Upgrade Component of the TB Elimination Cooperative Agreements will be to build on past improvements to facilitate development of a system to provide timely and reliable laboratory testing for TB treatment and control efforts. To assist laboratories in this endeavor, Laboratory Upgrade funds will be awarded based on plans for, and progress toward, (1) meeting CDC recommended turnaround times (Tenover, *et al.* 1993. J. Clin. Microbiol. *31*:767–770 and Styrt, *et al.* 1997. J. Clin. Microbiol. *35*:1401), (2) accomplishing the Healthy People 2010 TB Laboratory goal (laboratory confirmation of a case of tuberculosis within 48 hours of specimen receipt for 75 percent of cases that are ultimately culture-confirmed), and (3) developing a system that ensures optimal use of laboratory services and effective reporting of information.

To accomplish this goal and sustain past improvements, Laboratory Upgrade Program funds will be awarded in FY05 to eligible applicants, with one-third of these funds going toward accomplishing each of the three laboratory component objectives listed below.

Component 1: Meeting Recommended Turnaround Times

Many recipient laboratories have already met the recommendations for activities and turnaround times. Continued support is needed to sustain the improvements and to enable all laboratories to meet all recommendations. Because the cost of accomplishing this component depends on the number of tests performed, funds for this component will be distributed on a ''per patient reported basis''.

Component 2: Accomplishing the Healthy People 2010 Goal

On the surface, this goal appears to be a daunting challenge for the public health laboratory both on the technical level and budgetary level. However, technologies are readily available on the market that could accomplish this goal and the cost of incorporating such technologies may not be as high as many fear. Much of the anticipated cost comes from the idea that any new test would inevitably be a test that must be added to whatever testing the laboratory is currently doing. To counter this, laboratories should consider novel testing algorithms that might enable cost-effective incorporation of new tests into their testing algorithm and workflow. Laboratories considering a new testing algorithm should consult with clinicians and TB controllers as to the acceptability of a new testing algorithm and should collect data to allow the performance and cost of the new testing algorithm to be compared to the current testing algorithm. Because the cost of accomplishing this component depends on the number of tests performed, funds for this component will be distributed on a ''per patient reported basis''.

Component 3: Developing an Integrated System That Ensures Timely Laboratory Testing and Timely Flow of Information

To provide guidance for accomplishing this goal, the Association of Public Health Laboratories (APHL) and CDC commissioned a Task Force on the Future of TB Laboratory Services. The Task Force included representatives from APHL, CDC, public health laboratories, hospital and commercial laboratories, and the National TB Controllers Association (NTCA). Its charge was to define and address issues critical to those who perform TB testing and those who use the test results and to develop recommendations for improving TB treatment and control through optimal use of laboratory services and effective reporting and tracking of information. The report of this task force will be made available to applicants. It provides guidance on specific action items and performance measures necessary to develop and implement an integrated system for providing laboratory services. Because the cost of accomplishing this component should be about the same for each program, funds for this component will be distributed on a ''per program'' basis (*i.e.*, an equal amount to each recipient).

I.3. Awardee Activities

Awardee activities for this program are as follows:

A. TB Prevention and Control

(1) Treatment and Case Management of Persons With Active TB

• Ensure case management and treatment of persons with active TB through the use of adherence-promoting measures such as cohort analysis, outreach staff, extensive application of directly observed therapy, incentives, and enablers.

• Assess reasons for non-adherence with TB treatment, both for patients not completing therapy and for patients with delayed completion of therapy. Devise individual and programmatic interventions to increase completion of therapy and improve timely completion of therapy.

• Assess adequacy and appropriateness of therapy for each patient by reviewing initial regimen, susceptibility results, adherence, and response to therapy. Therapy should be consistent with American Thoracic Society/Infectious Disease Society of America/Centers for Disease Control and Prevention guidelines. Refer to the following Web link for more information. *http://www.cdc.gov/nchstp/tb/*.

• Collaborate with HIV/AIDS programs to ensure that all newly diagnosed TB cases are counseled and tested for HIV and referred for HIV services if found to be HIV positive.

• Collaborate with substance abuse and homeless programs to ensure all newly diagnosed TB cases are evaluated and treated for TB.

• Ensure that immigrants and refugees classified as A, B1, or B2 are located promptly and evaluated and treated appropriately. Refer to ''Medical Examination of Aliens and Technical Instructions'', page six, at the following Web link. *http://www.cdc.gov/ncidod/dq/panel.htm*.

• Develop and implement the appropriate use of the Binational TB Card and appropriate referral systems for patients who may receive care along the U.S.-Mexico border or who may cross the border while under treatment for TB.

• Ensure that effective interventions are implemented to identify foreign-born and U.S. minorities at highest risk for developing TB and that they are evaluated and treated for TB or TB infection.

• Establish a systematic process to routinely evaluate case management activities to ensure optimal program performance.

(2) Contact Investigation

• Ensure that contact investigation activities are initiated and completed promptly, including interviewing TB cases to identify contacts, evaluating contacts for latent TB infection and disease, and ensuring infected contacts begin and complete an appropriate course of treatment for latent TB infection.

• Assess reasons for cases with no contacts identified or a low number (*e.g.*, less than three) of contacts identified, delays in interviewing cases or evaluating contacts, and low completion of preventive therapy rates, and devise strategies for improvement. Combine epidemiologic data with TB genotyping results, where appropriate, to confirm or identify previously unidentified transmission links between TB cases and use genotyping results to evaluate the completeness of contact investigations.

• Cooperative agreement recipients will submit data from contact investigations in the Aggregate Reports for Tuberculosis Program Evaluation (ARPE): Follow-up and Treatment of Contacts to Tuberculosis Cases, in accordance with the schedule in Attachment 2 (or via such reports that will supercede ARPEs as developed and agreed between CDC and the National Tuberculosis Controllers Association.)

(3) TB Surveillance/Reporting

• Enhance identification, reporting, and follow-up of TB cases and suspects by establishing liaisons with appropriate reporting sources such as hospitals, clinics (*e.g.*, TB and HIV/AIDS clinics), laboratories performing tests for mycobacteria, selected physicians (*e.g.*, pulmonary and infectious disease sub-specialists), correctional facilities, community and migrant health centers, pharmacies, and other public and private facilities providing care to populations with or at risk for TB. States should provide periodic feedback to reporting sources, and at least annually provide a written report summarizing TB surveillance data.

• Develop and implement active surveillance activities to ensure complete and timely reporting of TB cases and suspects. At minimum, ongoing active laboratory surveillance should be conducted in all areas to ensure complete reporting of all TB cases and suspects with positive acid-fast bacilli (AFB) smears and cultures for *M. tuberculosis* complex.

• Maintain a registry of TB cases that the jurisdiction will include in its morbidity total that contains at a minimum the elements to produce data for the national TB case report, Report of Verified Case of Tuberculosis (RVCT). All local jurisdictions should also have at least a log, if not a registry, that contains key demographic and clinical information on each reported TB suspect. It is also recommended that TB cases receiving diagnostic, treatment, or contact investigation services in the local jurisdiction, although not included in the annual morbidity total, be included in the TB registry.

• Incorporate quality assurance policies and procedures into the maintenance operations of the TB registry to ensure complete and reliable data.

• Routinely analyze (*e.g.*, quarterly) TB surveillance data to monitor trends, detect potential outbreaks, and define high-risk groups, and produce and disseminate at least an annual report summarizing current data and trends.

• Routinely (*e.g.*, annually) evaluate programmatic performance by using TB surveillance data to assist in compiling supporting evidence to determine the extent to which program objectives are being met and also to assist in developing strategies for improvement.

• Ensure that TB surveillance data are kept confidential and that all data files are secure. Policies and procedures must be in place to protect the confidentiality of all surveillance case reports and files. Policies and procedures to protect HIV test results must conform to the confidentiality requirements of the state and local HIV/AIDS programs.

• Report all TB cases to be included in the annual morbidity total to the CDC according to a schedule agreed upon each year, generally monthly, and at least annually. TB case data will be reported to CDC using the RVCT form via an electronic format that conforms to Public Health Information Network (PHIN) and/or National Electronic Disease Surveillance System (NEDSS) messaging standards, or prior to the complete transition to NEDSS for national TB reporting, using the CDC provided software, the Tuberculosis Information Management System (TIMS).

• Periodically (*e.g.*, at least every two years) evaluate the completeness of reporting of TB cases to the surveillance system by identifying and investigating at least one population-based secondary data source (*e.g.*, statewide laboratory record review, pharmacy review, hospital discharge data review) to find potentially unreported TB cases. Potential TB cases identified during the evaluation must be verified through review of medical records, physician interviews, or patient interviews. Reasons for non-reporting of TB cases should be determined and a plan for

improvement developed and implemented.

• Collaborate with the HIV/AIDS program to conduct at least annual TB and AIDS registry matches to ensure completeness of reporting of HIV and TB co-infected patients to both surveillance systems. Investigate and verify all TB cases reported to the HIV/AIDS program and not reported to the TB program. Update the TB registry as indicated.

• Periodically (*e.g.*, annually) assess reasons for incomplete HIV results on the RVCT for each verified case of TB. Determine if patients were not tested for HIV or were tested but results not reported to the TB program. Develop and implement plans for improvement.

• Periodically (*e.g.*, annually), evaluate the validity of RVCT data, focusing particularly on drug susceptibility test results and other laboratory data, by comparing TB registry data to original data sources. Develop and implement plans for improvement.

• Establish a systematic process to routinely evaluate activities related to surveillance and reporting to ensure optimal program performance.

(4) Human Resource Development

States and big city TB programs receiving funding should assign someone to serve as a focal point for training within the TB program. This person should be (or become) an active participant in the Tuberculosis Education and Training Network (TB ETN) in order to increase and develop knowledge and skills, increase awareness of resources available, and actively participate in determining needs and developing high priority resources for TB control and elimination. States and big cities receiving funding should develop a Training/Human Resource Strategy Plan to:

• Establish and improve existing in-service TB training and human resource development.

• Establish evaluation strategies to improve existing systems and to identify ongoing training and human resource needs.

• Establish and improve patient education and communications capacity within the program.

• Coordinate training related to TB control with training for other disease control interventions such as HIV/AIDS and STD.

• Target other health care providers or organizations serving high-risk populations.

Technical assistance on developing a state or local Training and Human Resource Strategy Plan will be provided via the TB ETN and/or the RTMCCs after award of funds. Utilization of funds for training external to the TB program (*e.g.*, National Jewish Clinical Course, or a RTMCC Course) should be limited to courses that cannot be delivered by the TB program as determined by course content and job responsibilities of the participant; this external training need must be specified in the Training/Human Resource Strategy Plan.

For identified high priority needs, such as an outbreak or identified case in a high-risk setting, additional funding and assistance may be provided as needed via the DTBE Outbreak Response Plan. Organizations, programs such as state TB control programs with training capacity, or one of the RTMCCs could be utilized via a contract method to deliver training and human resource development in this low incidence area to address identified outbreak response needs.

(5) Program Evaluation Activities

All grantees should actively engage in self-evaluation to ensure that their findings guide the program in making necessary changes to more effectively carry out their mission of TB prevention and control.

• By Fall of 2005, all grantees will be required to submit to CDC an evaluation plan that explains their process for program assessment, defines the methods used for program self-evaluation, and how they plan to provide technical assistance to local programs that grantees should actively engage in self-evaluation and use findings to guide the program in making necessary changes to more effectively carry out their mission of TB prevention and control. Findings should also be used to evaluate the effectiveness of their own TB efforts. The evaluation plan should be based on a systematic approach, such as that provided in the CDC's Framework for Program Evaluation in Public Health [MMWR 1999:48 (No. RR11)]. Refer to Web link: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm.*

• All evaluation efforts should ensure that the diverse perspectives of relevant stakeholders (*e.g.*, TB program staff and managers, other service providers, patients and community representatives) are represented throughout the process. Grantees should also cultivate partnerships to expand their evaluation capacity.

• All grantees will use core performance measurements to assess program performance.

• As part of their evaluation plan, all grantees should select the performance measurements to evaluate their program's performance and provide baseline program data for selected indicators. The selected performance measurements must include, but are not limited to:

• TB Cases: the proportion that complete treatment within 12 months (among those with rifampin-sensitive TB).

• Contacts: the proportion of eligible contacts that start treatment, and of those who start treatment, the proportion that complete treatment.

• Immigrants and Refugees: the estimated proportion of immigrants and refugees classified as A, B1, or B2 eligible for treatment who start treatment, and of those who start treatment, the proportion that complete treatment.

• Case rates of African Americans (U.S.-born black non-Hispanic).

• Surveillance: the percentage of TB case reports in which 90 percent of the core data items are complete.

• In consultation with the CDC program consultants, grantees will set benchmarks and timelines for each selected measurement. In addition, as part of the grantees' evaluation plan, local and state indicators should be selected from a library of program indicators (or use locally tailored indicators of program performance) that reflect the demographic features of the TB in their jurisdiction, the resources available, and the capacity of the program to implement changes. Findings from the evaluation should be used to guide program development.

• Annually thereafter, grantees will submit, as part of the cooperative agreement continuation application, progress report data supporting progress toward meeting their goal for each program indicator. Where a goal has not been met, the grantee should provide an analysis of the factors leading to non-achievement of their objective and a plan and timeline for making progress toward achieving the objective. Monitoring progress toward meeting the self-designated goals for the program indicators will be the responsibility of the grantee in conjunction with the CDC program consultant.

• Project areas are accountable for achieving the target levels of performance established in their plans. If a project area fails to achieve their target, the project will need to submit as part of subsequent year funding applications, a plan to improve performance and achieve objectives.

B. RTMCCs

(1) Training and Technical Assistance

• Spend approximately 50 percent of their total effort and resources on training courses and training technical assistance, with primary emphasis on state and big city TB programs in their assigned geographic region. Each RTMCC, although part of the national network, will primarily serve a specific geographic region.

• Provide core courses based on a standardized curriculum developed in collaboration with the CDC and other RTMCCs. These courses should include, but are not limited to, program management training, supervisor training, outbreak response planning, case management, and program evaluation.

• Develop specialty courses, in addition to the core courses, that are unique to the needs of the region served or the area of expertise of the RTMCC.

• Both core and specialty course development should occur in consultation with CDC and be derived from recommendations and needs assessments from multiple sources, including: (1) CDC identified needs and priorities; (2) local and regional needs assessments; (3) the National Strategic Plan for Education and Training; and (4) new and existing national guidelines.

• Provide at least 400 hours of training each year. Training can take place at the RTMCC, but at least 30 percent of the training should take place in other settings, preferably in other states and in conjunction with regional TB controllers' association meetings.

• The RTMCCs should strive to develop the training capacity of local and state TB programs. In this activity, the RTMCCs will provide technical assistance, but will not be the principal organizer of training activities. As such, the RTMCCs will be responsible for the development of facilitator-led training materials for use by these programs, as well as the provision of technical assistance on how to utilize and fully implement these materials to build capacity within the TB programs.

• Conduct on-going evaluation of all courses and document the results of their evaluations in annual reports. Evaluation should include measuring appropriate process indicators (*e.g.*, trainee demographics, quality of training), immediate training outcomes (*e.g.*, changes in knowledge, attitudes, and skills) and where possible, long-range impact (*e.g.*, changes in provider practice behavior, changes in service delivery).

• Each RTMCC must demonstrate the capacity and plans to host Mini-Fellowship trainings each year. The purpose of the Mini-Fellowship is to provide participants with first hand knowledge and experience about the role of public health agencies in carrying out TB control activities.

• RTMCCs should provide education and training consultation and technical assistance on an ongoing basis to all partners. This technical assistance can be provided via telephone, e-mail, or written consultation. Technical assistance can also be provided on site for less experienced training coordinators or where greater needs and fewer resources are available.

• The RTMCCs will be expected to work collaboratively with each other and CDC by participating in monthly conference calls, annual meetings, and ongoing consultations.

(2) Educational and Training Material Product Development

• Spend approximately 30 percent of their resources on educational and training material development, including materials used in training courses sponsored by the RTMCC. Submit to CDC proposals for development of materials that can be used regionally and nationally. Develop proposals based on previously discussed criteria.

• Emphasis of product development should be to increase the capacity of local and state TB program personnel, TB training focal points, and TB ETN members to deliver high quality, competency based training and education. Facilitator led training materials should be a special focus of product development.

• Submit to CDC proposals for development of materials that can be used regionally and nationally. Develop proposals based on previously discussed criteria and collaboration and input from CDC and other RTMCCs.

• Utilize distance learning strategies in course or product development. Create materials in multiple formats (*e.g.*, print and electronic formats) to meet the varied needs of the intended target audiences.

• RTMCCs will be responsible for initial production and distribution of products. For products that are needed in large quantities, RTMCCs can submit these products through the CDC/Division of Tuberculosis Elimination (DTBE) clearance process. If approved, DTBE will be responsible for printing and distribution of these materials.

• Develop and maintain a Web site containing, at minimum, a list of courses and materials offered by the RTMCC, as well as ordering information. In addition, electronic versions (HTML and PDF) of products developed by the RTMCC should also be posted on the Web site.

Note: Materials developed by the RTMCCs must be in the public domain and cannot be copyrighted. Furthermore, CDC reserves the right to make additional changes to materials or products produced by the RTMCCs that will be distributed nationally.

• RTMCCs should acquire or make provisions to award continuing education credits, including Continuing Medical Education (CME), Continuing Nursing Education (CNE), Continuing Education Units (CEU), and Continuing Health Education Credits (CHES) when possible and appropriate for training and educational products.

(3) Medical Consultation

• Spend approximately 20 percent of their time and resources on activities related to medical consultation, including the activities listed below.

• Provide real-time medical consultation, in the region assigned by CDC, to physicians and other providers of medical care on the diagnosis and treatment of TB disease, including MDR-TB. Consultation should also be provided on the diagnosis and treatment of LTBI, including persons presumed to be infected with drug resistant strains of *M. tuberculosis.*

• Develop a strategy to appropriately promote this medical consultation service to healthcare providers in the assigned region.

• Evaluate the effectiveness of medical consultation service and document the results of the evaluation in the annual reports.

• Conduct a needs assessment in the assigned region for current and future needs for consultation related to the medical evaluation and management of persons with TB disease and LTBI. (Year 1 of the funding period.)

• Develop a regional plan, in consultation with regional TB control programs, CDC, and other interested parties to address current and future regional needs for consultation related to the medical evaluation and management of TB disease and infection in the assigned region. (Years 1 and 2 of the funding period.)

• Implement relevant sections of regional plan in consultation with regional TB control programs and CDC. (Years 3–5 of funding period.)

C. TB Public Health Laboratory

(1) Develop and implement plans to ensure availability of reliable, timely TB laboratory services and to meet or make progress towards meeting CDC recommended turnaround times

(Tenover, *et al.* 1993. J. Clin. Microbiol. *31*:767–770 and Styrt, *et al.* 1997. J. Clin. Microbiol. *35*:1401). Use recommended methods for the isolation, identification, and susceptibility testing for *M. tuberculosis* complex appropriate to the individual laboratory's workload and experience. Ensure rapid reporting of results (smear, culture, susceptibility results) to the TB control program and to the submitting health care provider.

(2) Develop and implement plans to meet, or make progress towards meeting, the Healthy People 2010 TB Laboratory goal. The goal is laboratory confirmation of a case of tuberculosis within 48 hours of specimen receipt for 75 percent of cases that are ultimately culture-confirmed.

(3) Develop and implement plans to create a system to provide timely and reliable laboratory testing for TB treatment and control efforts. Key steps will include to (a) assess the structure, performance, and cost of the current network of laboratory service providers and users, (b) develop a referral and information network to ensure reliable testing and the timely flow of specimens and information, and (c) use quality improvement principles to continually evaluate and improve the performance of the laboratory service network.

I.4. CDC Activities

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC activities for this program are as follows:

A. TB Prevention and Control

- Provide consultation and technical assistance in setting priorities, establishing partnerships, and planning, conducting, and evaluating TB prevention and control activities.
- Provide up-to-date information on the recommendations and guidelines for diagnosis, treatment, follow-up, surveillance, and prevention of TB.
- Provide assistance to improve systems that monitor surveillance, prevention and control activities.
- Facilitate the technological and methodological transfer of successful prevention and intervention models among project areas, *e.g.*, workshops, conferences, written communications.
- Assist recipients in monitoring program evaluation/performance, setting and meeting objectives, implementing methods, and complying with cooperative agreement requirements and other funding issues, through various methods including telephone consultation, site visits (and expanded site visits when appropriate), and site visit reports.
- Provide consultation and technical assistance for tuberculosis outbreaks, including on-site support of investigations when requested by the state health department.
- Provide technical assistance in assessing and prioritizing training and education needs and in planning, implementing and evaluating training and education activities.
- Coordinate cross-program collaborative approaches to HIV, STD and TB prevention and intervention when indicated and appropriate.
- Support individual recipients by providing technical assistance in the development and evaluation of new or innovative approaches to TB control, including behavioral or health systems interventions.
- Establish and maintain effective working relationships with a TB elimination advisory committee for the purpose of formulating and implementing a plan for the elimination and interruption of transmission of TB.
- Provide tools, educational materials, and technical assistance to help implement the national program evaluation initiative.

B. RTMCCs

- Within three months of funding (notice of grant award), CDC will convene a meeting of all funded RTMCCs to outline a comprehensive plan for collaboration between the RTMCCs and CDC.
- Provide consultation and technical assistance in setting priorities, establishing partnerships, and planning, conducting, and evaluating training and medical consultation activities and education and training materials.
- Conduct annual site visits to review training capabilities and products, advise on instructional design and curriculum and product content, provide technical assistance, and review resource allocations and budgets.
- Participate in regularly scheduled telephone conference calls.
- Monitor program implementation, project management, and evaluation activities.
- Provide up-to-date information on the CDC/ATS recommendations and guidelines for diagnosis, treatment, surveillance, and prevention of TB.
- Facilitate the technological and methodological transfer of successful training and medical consultation models among the project areas.
- Facilitate collaboration between the RTMCCs and TB control programs in their designated geographic region.
- Serve as a liaison with the clearance process and the Management Analysis Services Office (MASO) for printing and distribution of educational products to be printed and distributed by CDC.

C. TB Public Health Laboratory

- Provide consultation and technical assistance in setting priorities, establishing partnerships, and planning, conducting, and evaluating TB laboratory activities.
- Provide up-to-date information on the recommendations and guidelines for diagnostic mycobacteriology and TB Laboratory services.
- Provide assistance to improve systems or networks that provide TB laboratory services.
- Facilitate the technological and methodological transfer of successful laboratory service models among project areas, *e.g.*, workshops, conferences, written communications.
- Assist recipients in monitoring program evaluation and performance, setting and meeting objectives, implementing methods, and complying with cooperative agreement requirements and other funding issues, through various methods including telephone consultation, site visits (and expanded site visits when appropriate), and site visit reports.
- Provide technical assistance for participation in the program for DNA genotyping of *M. tuberculosis* isolates.
- Provide consultation and technical assistance for laboratory aspects of tuberculosis outbreaks and for laboratory investigations, including on-site support of investigations when requested by the state health department.
- Support individual recipients by providing technical assistance in the development and evaluation of new or innovative approaches to providing TB Laboratory services.
- Establish and maintain effective working relationships with laboratory advisory committees including the Association of Public Health Laboratories for the purpose of formulating and implementing a plan for the provision of reliable tuberculosis laboratory services.

II. Award Information

Type of Award: Cooperative agreement. (CDC involvement in this program is listed in section ''I.4. CDC Activities'' above.)

Fiscal Year Funds: FY 2005.

A. TB Prevention and Control

Approximate Total Funding: $85.0 million. Approximately $83 million will be available in FY2005 for core TB prevention and control activities (completion of therapy, contact

investigation, and TB surveillance). Approximately $2 million in additional funds are expected to be available in FY2005 for training, education, and human resource development.

Approximate Number of Awards: 68.

Approximate Average Award: $1,200,000. (This amount is for the first 12-month period, and includes both direct and indirect costs.) Programs reporting 50 or fewer TB cases annually will receive $20,000 in supplemental funding for TB training and education. Programs reporting 51–500 TB cases annually will receive $30,000 in supplemental funding for TB training and education. Programs reporting greater than 500 cases annually will receive $50,000 in supplemental funding for TB training and education.

Floor of Award Range: $50,000.

Ceiling of Award Range: $15,000,000.

Anticipated Award Date: January 1, 2005.

Budget Period: 12 months.

Project Period Length: Five Years.

B. RTMCCs

Approximate Total Funding: $7.5 million.

Approximate Number of Awards: 3–5.

Approximate Average Award: $1,500,000. (This amount is for the first 12-month period, and includes both direct and indirect costs.)

Floor of Award Range: $1,500,000.

Ceiling of Award Range: $2,500,000.

Anticipated Award Date: January 1, 2005.

Budget Period: 12 months.

Project Period Length: Five years.

C. TB Public Health Laboratory

Approximate Total Funding: $7.9 million.

Approximate Number of Awards: 62.

Approximate Average Award: $130,000. (This amount is for the first 12-month period, and includes both direct and indirect costs.) Laboratory Upgrade Program funds will be awarded in FY05 as follows: 80 percent of FY05 funds will be awarded based on FY04 funding level (*i.e.*, each recipient will receive 80 percent of their FY04 base funds) and the remaining 20 percent of FY05 funds will be distributed to recipients on a ''per patient reported to the TB control program'' or a ''per program'' basis with one-third of these funds going toward accomplishing each of the three laboratory component objectives.

Floor of Award Range: $5,000.

Ceiling of Award Range: $960,000.

Anticipated Award Date: January 1, 2005.

Budget Period: 12 months.

Project Period Length: Five years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

III. Eligibility Information

III.1. Eligible Applicants

A. TB Prevention and Control

Applications may be submitted by health departments of States or their *bona fide* agents, including the District of Columbia; the Commonwealths of Puerto Rico, Virgin Islands, and Northern Mariana Islands; American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau; and the cities of Baltimore, Chicago, Detroit, Houston, Los Angeles, New York, Philadelphia, San Diego, and San Francisco. The nine cities were the only original sites funded by CDC TB Cooperative Agreement dollars. When CDC expanded TB funding to State and territorial TB programs, the agency continued to fund the cities as separate project areas with the concurrence of the States in which they are located.

A *bona fide* agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a State application. If you are applying as a *bona fide* agent of a State or local government, you must provide a letter from the State as documentation of your status. Place this documentation behind the first page of your application form.

B. RTMCCs

See III.1.A. above.

C. TB Public Health Laboratory

See III.1.A. above.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Note: Title 2 of the United States Code 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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity, use application form CDC 1246. Application forms and instructions are available on the CDC Web site, 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) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Application

You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: There is a maximum of 30 pages for TB Prevention and Control Activities, 30 pages for the Regional TB Training and Medical Consultation Centers, and 10 pages for the TB Public Health Laboratory. If your narrative exceeds the page limit, only the pages which are within the page limit will be reviewed. Budget justifications will not be counted in the stated page limits.
- Number all pages sequentially.
- Include a table of contents.
- Font size: 12 point unreduced.
- Single spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Header on each page: Program name, grant number.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period. Use the information in the Awardee Activities (section I.3.) and Application Review Criteria (section V.1.) sections to develop the application content, and you must include the following items in the order listed.

A. TB Prevention and Control Activities

- Program need.
- Objectives.
- Methods.
- Evaluation.
- Budget Justification (not included in narrative page limit).

B. RTMCCs

- Introduction/Program Description.
- Methods: Training, Technical Assistance and Educational/Training Product Development.
- Methods: Medical Consultation.
- Evaluation.
- Objectives.
- Budget Justification (not included in narrative page limit).

C. TB Public Health Laboratory

The President's Management Initiative requires that programs that receive Federal funds include in their proposals clearly stated goals and objectives for which the program will be held accountable and performance measures by which progress toward accomplishment of goals can be assessed. For the Laboratory Upgrade Program, applicants are requested to describe realistic achievable goals for each of the key components of the program. Although the ultimate goals for each component of the Laboratory Upgrade Program are described in this announcement, it is not anticipated that all programs will be able to accomplish all goals in the first year of the cooperative agreement, or perhaps, even during the 5-year project period. Therefore, programs are encouraged to set time-phased, realistic, achievable goals and describe appropriate milestones toward achieving the ultimate goals. Performance measures should be described that will allow assessment of progress towards each of the goals and/or milestones set by the program.

Provide a report describing the number of confirmed TB cases for which the laboratory provided any test result to the TB control program that was used to complete the RVCT form during each of the three calendar years preceding the application and the current (partial) year. For the FY05 application, report the numbers for the full calendar years of 2001, 2002, and 2003, and any available data for 2004. For a case to be counted, the laboratory must have reported to the TB control program at least one of the following pieces of information: isolation of *M. tuberculosis* from a patient specimen; identification of *M. tuberculosis* from a specimen, culture, or referred isolate; or drug susceptibility results from a culture or referred isolate.

Include a description of the current laboratory activities and performance, which should include the following:

(1) A brief description of the methods used in the laboratory, and include work load and work flow in the laboratory and any written policies to eliminate redundant or unnecessary testing. The description of the laboratory work load in 2003 and 2004 (to date) should include the following (this can be in a tabular form):

(a) Number of patients for whom the laboratory confirmed an initial diagnosis of TB by culturing *M. tuberculosis* from a primary patient specimen (*e.g.*, sputum, CSF, biopsy, etc,).

(b) Number of patient specimens processed and cultured.

(c) Number of patients for whom cultures were processed for mycobacterial identification testing, and/or whose isolates were referred to other laboratories for identification testing.

(d) Number of patients whose specimens produced cultures containing any species of *Mycobacterium*.

(e) Number of patients whose specimens produced cultures containing *M. tuberculosis*.

(f) Number of patients for whom *M. tuberculosis* drug susceptibility tests were performed and/or whose isolates were referred to other laboratories for susceptibility testing.

(g) Number of patients for whom nucleic acid amplification tests confirmed the presence of *M. tuberculosis* in a primary patient specimen.

(2) A brief description of progress towards meeting CDC recommendations as described in Tenover, *et al.* and Styrt, *et al.* Each of the following recommendations should be addressed in the narrative, including laboratory methods used and current turnaround times (TAT) for initial diagnostic specimens described in the narrative or in a tabular form:

(a) Promote rapid delivery of specimens to the laboratory (goal TAT is 24 hours from collection of specimen).

(b) Use fluorescent acid-fast staining and promptly transmit results by phone, FAX, or electronically. (goal TAT is 24 hours from receipt of specimen).

(c) Inoculate a liquid medium as one of the primary cultures.

(d) Identify growth as acid-fast and use rapid methods to identify isolates as *M. tuberculosis* as soon as possible (goal TAT is 14–21 days from receipt of specimen).

(e) Determine the susceptibilities of initial *M. tuberculosis* isolates to primary drugs in a rapid culture system (goal TAT is 21–28 days from receipt of specimen).

(f) Report the results of drug susceptibility testing to the clinician as soon as they are available by phone, FAX, or electronically.

(3) Describe baseline activities and any progress on accomplishing the Healthy People 2010 goal of the laboratory confirmation of TB within 48 hours of specimen receipt for 75 percent of TB cases that are ultimately culture-confirmed.

(a) Number and percent of specimens received by the laboratory within 24 hours of collection.

(b) Number of patient specimens tested using rapid detection and identification tests (*e.g.*, MTD tests or nucleic acid amplification tests).

(c) Number of patients for whom laboratory confirmation of TB was provided within 48 hours.

(d) Number of patients for whom the laboratory confirmed TB by isolation of *M. tuberculosis* from a patient specimen.

(4) An update on TB public health laboratory recipient activities to include a description of any modifications to Laboratory goals and objectives, any obstacles encountered and/or reasons for failing to meet established objectives, future plans and objectives, and other pertinent information, such as laboratory facility or staffing changes, high costs for performance of objectives, plans to minimize costs, etc.

Component 1: Accomplishment of CDC Recommended Laboratory Activities and Turnaround Times

- Program need.
- Objectives.
- Methods.
- Evaluation.
- Budget Justification. (*See* below for additional guidance.)

Component 2: Accomplishment of the Healthy People 2010 TB Laboratory Goal

- Program need.
- Objectives.
- Methods.
- Evaluation.
- Budget Justification. (*See* below for additional guidance.)

Component 3: Development of a System To Provide Timely and Reliable Laboratory Testing in Support of TB Treatment and Control Efforts

- Program need.
- Objectives.
- Methods.
- Evaluation.
- Budget Justification. (*See* below for additional guidance.)

For the Public Health Laboratory portion, two budget proposals are

requested: (1) Budget reflecting true needs: a combined budget should be provided that includes all projected costs associated with conducting all components of the Laboratory Upgrade Component. A combined budget is requested because some activities support more than one component. (2) Budget reflecting anticipated funding level. A combined budget reflecting the anticipated funding level should be provided. Applicants should assume that they will receive 80 percent of their base award for the FY04 TB Cooperative Agreement plus $50 per patient reported for Component 1 (recommended activities and turnaround times) plus $50 per patient reported for Component 2 (Healthy People 2010 goal) plus $6000 for Component 3 (laboratory system development). Please note that the amounts for Components 1 and 2 will be awarded based on the average yearly number (3-year average) of confirmed TB cases for which the laboratory provided any test result to the TB control program that was used to complete the RVCT form. The precise ''per patient reported'' amount is not yet known and will depend on the total number of cases reported on by all recipient laboratories in the U.S. If one assumes that the public health laboratories report information on all culture-positive cases within their TB programs, funds for Components 1 and 2 would be awarded at $50 per patient reported. Funds available for Component 3 will depend on the number of technically acceptable applications received. The $6,000 assumes that all laboratories will submit acceptable proposals.

In addition to the information provided in the sample guideline, please include the following specific for the Laboratory Upgrade program:

Salaries and Wages

For each TB lab position for which full or partial funding is requested, indicate whether the position is ''continuation funding'' or ''new request for funding''. If the position is a ''new request for funding'', state whether the position is new to this program or a continuation position previously funded by another source (describe source), and provide complete justification for the need to establish a new position based on specific program objectives.

Equipment

Laboratory equipment should be listed in priority order, with the first item being of highest priority. Provide a justification of the need for the equipment. Items of equipment are considered one-time expenditures separate from the base budget; therefore, funding decisions will be based primarily on the availability of funds and the priority of needs based on the justifications provided.

Supplies

When requesting TB lab upgrade supplies, consolidate them by relevant item groups (*e.g.*, (a) Microscopy, (b) Liquid Culture, (c) Identification, (d) Drug Testing, *etc.*) with the dollar amounts for each group. Do not use item groups such as Miscellaneous Lab Supplies or General Office Supplies. These type of items are not appropriate for funding under this program. Provide justification for each item and relate to specific laboratory activities.

Travel

Dollars requested for travel for TB lab staff should be justified for reasons pertaining to specific program objectives (*e.g.*, training in TB Lab Upgrade recommended activities, site visits to develop a laboratory network). Please provide details about the training course(s) in the justification. Meeting and conference attendance are not considered training under this lab upgrade program.

For All Activities

Indirect Costs

Provide the date of the most recent indirect cost rate agreement, the rate or percentage, and the cost on which the rate is computed. Please attach a copy of the most recent and/or current indirect cost rate agreement. Indirect costs cannot be requested at a percentage greater than the approved rate, but can be requested at a percentage less than the approved rate.

Direct Assistance

You may request Federal personnel as direct assistance (DA), based on an identified need and pending the availability of funds. DA funding will be administered separately and *will not* be a part of your base award. To request a Federal assignee for new position, provide sufficient information for CDC to develop and grade a position description.

To request new direct-assistance assignees, include:

a. Number of assignees requested.

b. Description of the position, proposed duties, and supervisory responsibilities.

c. Ability or inability to hire locally with financial assistance.

d. Justification for request.

e. Organizational chart and name of intended supervisor;

f. Opportunities for training, education, and work experiences for assignees.

g. Description of assignee's access to computer equipment for communication with CDC (*e.g.*, personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office).

h. A signed Agreement to Detail form.

State and Local Contributions

As part of the application process, the grantee will be required to provide the amounts of State and local contributions for TB prevention, control, and elimination by budget category. Refer to Attachment 5.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information should be limited to the following:

- Letters of Support.
- Organizational Charts.

Any additional materials will not be reviewed.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. For more information, *see* the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm*. If your application does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may necessitate you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National policy Requirements.''

IV.3. Submission Dates and Times

Application Deadline Date: July 26, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC

receives your application 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, you will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This program announcement is the definitive guide on application format, content, and deadlines. It supercedes information provided in the application instructions. If there are discrepancies between the application form instructions and the program announcement, adhere to the guidance in the program announcement.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html*.

IV.5. Funding Restrictions

Restrictions that must be taken into account while writing your budget are as follows:

Categorical funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Emphasis must be given to directing the majority of funds to first-line TB control activities. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant State or local health department funds or for inpatient care or construction of facilities. Funds may not be used to purchase drugs for treatment.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs. Guidance for completing your budget can be found in attachment 2 of this announcement as posted on the CDC Web site.

IV.6. Other Submission Requirements

Application Submission Address: submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management–PA# 05003, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Each activity category will be reviewed and scored separately. Specific criteria for each activity category are as follows:

A. TB Prevention and Control Activities

All technically acceptable applications will be funded for TB prevention and control activities. The following criteria will be used to evaluate applications for their technical acceptability.

(1) Objectives: (30 percent) The proposed program objectives are measurable, specific, time-phased, and related to the recipient activities, program purpose, and program need, and the proposed progress toward the applicable national TB objectives is appropriate and feasible.

(2) Methods: (30 percent) The proposed strategies and activities are appropriate and feasible to achieve the stated program and applicable national objectives.

(3) Program need: (20 percent) The applicant demonstrates program need for TB prevention and control activities in terms of annual number of reported TB cases (and case rates), TB suspects (patients started on TB treatment but later determined not to be a TB case) per verified case, and Class A, B1, and B2 notifications. In addition, the program demonstrates the contribution of factors, such as HIV prevalence, drug resistance and multidrug resistance rates, TB in U.S.-born minorities, foreign-born persons, the homeless, and substance abusers, and the presence of barriers to achieving the applicable national TB program objectives.

(4) Evaluation: (20 percent) The evaluation plan is appropriate for measuring progress toward project and national TB objectives and identifying contributing factors when objectives are not met.

(5) Budget: (reviewed, not scored) The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to program success.

B. Regional TB Training and Medical Consultation Centers

These projects will be evaluated individually against the following criteria by an independent review group appointed by CDC. Funding preference will be given to applicants that ensure geographic distribution of centers.

(1) Methods: Training, Technical Assistance, and Educational/Training Product Development (40 percent). The extent to which the applicant provides: (a) A description of planned activities to determine the training and education needs of state and local health department staff, health care providers, and prevention specialists involved in TB control and elimination activities, including a description of the proposed process to update the training needs of target audiences in their coverage area; (b) a plan for acquiring CME, CEU, CNE, and CHES appropriate for trainees; (c) a description of available facilities and equipment for training and education; (d) a plan to produce course materials and for providing resources to trainees; (e) the proposed approach to developing the training plan based on the center's capability and the needs assessment, that will provide at least 400 hours of instruction per year; (f) a description of their ability to provide courses using distance learning technology; (g) a description of plans for providing technical assistance to training focal points, TB ETN members, and other trainers; and (h) a plan for the development of high priority educational and training materials, including the subject matter of the material, target audience, format, development process, and marketing and distribution.

(2) Methods: Medical Consultation (20 percent). The extent to which the applicant provides: (a) A description of the plan to determine the current and future needs for medical consultation in the jurisdictions in their assigned region in regard to appropriate medical evaluation and treatment of persons with active TB disease and latent TB

infection; (b) a description of and the appropriateness and quality of the plans to provide needed medical consultation; (c) a description of the plan to have physicians with appropriate expertise available to provide to consults; (d) a description of the infrastructure available to support medical consultation activities; and (e) a description of the plan to market their medical consultation services.

(3) Evaluation: (15 percent). The extent to which the applicant provides: (a) a plan for utilizing program evaluation data to provide continuous quality improvement of training activities and material development processes; (b) a plan for conducting evaluation activities that determine the impact, outcomes, and utilization of training activities and educational materials; and (c) a plan to evaluate the effectiveness and impact of medical consultation services.

(4) Introduction/Program Description: (15 percent). The extent to which the applicant provides: (a) a history of training experience and provision of technical assistance in training and education, and experience in product development; (b) a history of experience in providing TB medical consultation; (c) position descriptions for proposed RTMCC staff, including credentials and appropriate experience; (d) a proposed protocol for collaborating with regional, State, and local TB control programs, other RTMCCs, CDC, and TB–ETN members; and (e) a letter of endorsement from each university/college or health department partner stating their intent to participate in the RTMCC.

(5) Objectives: (10 percent) The extent to which the applicant provides specific, measurable, time-phased, realistic objectives.

(6) Budget: (reviewed, not scored): The extent to which the budget is reasonable, clearly justified, and consistent with the proposed plan.

C. TB Public Health Laboratory

All technically acceptable applications will be funded for TB Public Health Laboratory activities. The following criteria will be used to evaluate applications for their technical acceptability.

Component 1: Accomplishment of CDC recommended laboratory activities and turnaround times.

(1) Objectives (30 percent): Measurable, specific, time-phased, relevant, realistic objectives for attaining or maintaining CDC recommended laboratory activities and turnaround times are described and related to the recipient activities, program purpose, and program need. The timeline for the proposed progress toward the laboratory objectives is appropriate and feasible.

(2) Evaluation (30 percent): Specific performance measures and milestones are clearly described. The evaluation plan is appropriate for measuring progress toward objectives and identifying contributing factors when objectives are not met.

(3) Program need (20 percent): The applicant demonstrates a need for upgrading laboratory activities in terms of the current performance of the laboratory with respect to recommended activities and turnaround times and the annual number of confirmed TB cases for which the laboratory provided any test result that was used to complete the RVCT form. The recommendations are described above and in Tenover, *et al.* 1993. J. Clin. Microbiol. *31*:767–770 and Styrt, *et al.* 1997. J. Clin. Microbiol. *35*:1401.

(4) Methods (20 percent): The proposed strategies and activities are appropriate and feasible to achieve the stated objectives.

(5) Budget (not scored): The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to success.

Component 2: Accomplishment of the Healthy People 2010 TB Laboratory goal.

(1) Objectives (30 percent): Measurable, specific, time-phased, relevant, realistic objectives for attaining or maintaining the Healthy People 2010 TB Laboratory goal are described and related to the recipient activities, program purpose, and program need. The timeline for the proposed progress toward the laboratory objectives is appropriate and feasible. Short term goals may include efforts to promote rapid delivery of specimens to the laboratory or rapid testing for a subset of patients or specimens; and long term goals may include accomplishment of the Healthy People 2010 TB Laboratory goal.

(2) Evaluation (30 percent): Specific performance measures and milestones are clearly described. The evaluation plan is appropriate for measuring progress toward objectives and identifying contributing factors when objectives are not met.

(3) Program need (20 percent): The applicant demonstrates a need for attaining or maintaining the Healthy People 2010 TB Laboratory goal in terms of the current performance of the laboratory and annual number of patients for whom the program laboratory confirmed an initial diagnosis of tuberculosis by culturing *M. tuberculosis* from a primary patient specimen. The goal is laboratory confirmation of a case of tuberculosis within 48 hours of specimen receipt for 75 percent of cases that are ultimately culture-confirmed.

(4) Methods (20 percent): The proposed strategies and activities are appropriate and feasible to achieve the stated laboratory objectives.

(5) Budget (not scored): The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to success.

Component 3. Development of a system to provide timely and reliable laboratory testing in support of TB treatment and control efforts.

(1) Objectives (30 percent): Measurable, specific, timephased, relevant, realistic objectives for developing a system to provide timely and reliable laboratory testing in support of TB treatment and control efforts are described and related to the recipient activities, program purpose, and program need. The timeline for the proposed progress toward the laboratory objectives is appropriate and feasible. Short term objectives may include assessing the structure, performance, and cost of the current network of laboratory service providers and users; medium term goals may include developing a referral and information network to ensure reliable testing and the timely flow of specimens and information; and long term goals may include using quality improvement principles to continually evaluate and improve the performance of the laboratory service network.

(2) Evaluation (30 percent): Specific performance measures and milestones are clearly described. The evaluation plan is appropriate for measuring progress toward objectives and identifying contributing factors when objectives are not met.

(3) Program need (20 percent): The applicant demonstrates a need for developing a system to provide timely and reliable laboratory testing in support of TB treatment and control efforts.

(4) Methods (20 percent): The proposed strategies and activities are appropriate and feasible to achieve the stated laboratory objectives.

(5) Budget (not scored): The budget is reasonable, clearly justified, consistent with the demonstrated need and proposed activities, and likely to lead to success.

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of title 45 CFR part 46 for the protection

of human subjects? This will not be scored; however, 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.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by NCHSTP/DTBE. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above.

V.3. Anticipated Announcement and Award Dates

Awardees will be notified on or before January 1, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR part 74 and part 92.

For more information on the Code of Federal Regulations, *see* the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements.
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR–4 HIV/AIDS Confidentiality Provisions.
- AR–5 HIV Program Review Panel Requirements.
- AR–6 Patient Care.
- AR–7 Executive Order 12372 Review.
- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

A. TB Prevention and Control Activities

You must provide CDC with an original and two hard copies of:

(1) Annual Progress Report: The annual progress report summarizes the activities conducted during the previous budget period and documents the impact federally funded items have had in the achievement or progress of the goals and objectives of the project. This report is due 90 days after the end of the budget period (March 31). The annual progress report shall include:

(a) Brief project description.

(b) Overall program performance and progress of approved recipient activities as measured against the recipient activities outlined in the program's approved application and any subsequent amendments. Narrative describing major accomplishments in prevention and control activities in the project area. In addition, include a table with five years trends for all national objectives.

(c) Measures of Effectiveness: The grantee shall provide objective and measurable indicators that demonstrate the accomplishment of the various identified objectives of the award agreement. When a project is not meeting the specified objectives, a written discussion shall be included concerning how the activities were evaluated, the obstacles identified, and the proposed strategies to address the identified problem(s). It is recommended that the following format be utilized to convey this information:

Objective:

Status: (Met, Ongoing, Unmet)

Discussion:

(d) Overall Program Budget Issues: Identify any issues that may have or have had an impact on successful program performance.

(e) Financial Status Report due no more than 90 days after the end of the budget period.

(2) Interim Progress Report/Non-Competing Continuation Application: The Interim Progress report details the programmatic and fiscal activities conducted during the current budget period and documents the proposed activities and objectives for the upcoming new budget period. Current budget period activities are considered those activities initiated since the beginning of the current budget period to the date of the interim progress report. New budget period proposed activities are those for the following year's budget period. Submission of the completed Interim Progress Report and information requested in the Solicitation of Non-Competing Continuation Notification letter (*see* Attachment 4) shall constitute the grantee's non-competing continuation application. This report is due 90 days prior to the end of the budget period (September 30). The principal investigator shall sign the Interim Progress report. The project director and business office official shall sign the accompanying detailed budget and budget justification. The Interim Progress Report shall include:

(a) Current Budget Period Activities Objectives: For each objective, list the status, and provide a brief written discussion. Include in this discussion for each objective a description of lessons learned, barriers encountered, and how the barriers were addressed. Include a discussion of the reasons why goals were not met. Problems, delays, or adverse conditions, which materially impair the ability to meet the objectives of the award, shall be included in the discussion with a statement of action taken or contemplated and any assistance needed to resolve the situation. It is recommended that the following format be utilized:

Objective:

Status: (Met, Ongoing, or Unmet)

Discussion:

(b) Current Budget Period Financial Progress: Provide an estimate of the overall obligations for the current budget period.

i. If unobligated funds are anticipated at the end of the current budget period based on the current rate of obligation, provide detailed actions to be taken to obligate the estimated unobligated amount before the end of the current budget period, including the identification of vacant positions or contracts that have not been executed. If it is anticipated that the estimated unobligated amount will not be obligated by the end of the current budget period, the grantee can request that these unobligated funds be carried over to the new budget period if those unobligated funds are still required to support the program.

ii. If it is estimated that insufficient funding remains to support the project to the end of the current budget period, provide detailed justification of the

shortfall and the anticipated or taken actions to bring the obligations in line with the authorized funding level, or request supplemental funds.

(c) New Budget Period Program Proposed Activity Objectives:

List new proposed objectives for the upcoming budget period. These proposed objectives must support the intent of the original program announcement. Each objective shall be time-phased, measurable, and have a performance or outcome measure by which the success of the objectives can be assessed. For each objective, list proposed activities that will be implemented to accomplish the objective. Provide a timeline for objective accomplishment. If there is a redirection of activities, the grantee shall identify, justify and explain the methodology for the implementation of the redirection. The detailed line-item budget to support this proposed new budget period program activity, as requested in the Solicitation of Non-Competing Continuation Notification letter, shall be attached to the interim progress report.

(3) Final Financial Status Report and Final Progress Report due no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

B. Regional TB Training and Medical Consultation Centers

(1) Additional supporting documentation: As part of the annual TB Cooperative Agreement progress report (in a separate section), the grantee will be required to provide additional RTMCC supporting documentation in the following areas:

(a) List of regional training courses and medical consultation provided during the year.

(b) Evaluation data—Reports should include measuring appropriate process indicators (*e.g.*, trainee demographics, quality of training, distribution of products, Web use), immediate training outcomes (*e.g.*, changes in knowledge, attitudes, and skills) and where possible, long-range impact (*e.g.*, changes in provider practice behavior, changes in service delivery).

(c) Resource allocation—amount of human resource time (percent) and dollar expenditure for training, education, and medical and technical consultation activity should be provided. In addition, resource allocation for printing, travel, consultation services, and supplies should be provided. Breakdown of each RTMCC employee's percent effort on varied RTMCC activities.

(d) Summary of product distribution (including Web trends for Web-based products) and other evaluation data.

(e) Status of stated objectives.

(f) Strategies for marketing training, educational materials, and medical consultation services.

(g) Status of regional needs assessment for training and education and medical consultation including timelines for implementation of plans.

(h) Results of evaluations conducted on center activities.

(i) Listing of RTMCC activities not funded by CDC, and RTMCC employee efforts on such activities.

(2) Annual Progress Report: Refer to the Annual Progress Report section above, for reporting requirements.

(3) Interim Progress Report/Non-Competing Continuation Application: Refer to the Interim Progress Report/Non-Competing Continuation Application section above, for reporting requirements.

C. TB Public Health Laboratory

(1) Annual Progress Report: Refer to the Annual Progress Report section above, for reporting requirements.

(2) Interim Progress Report/Non-Competing Continuation Application: Refer to the Interim Progress Report/Non-Competing Continuation Application section above, for reporting requirements.

VII. Agency Contacts

For general questions about this announcement, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2700.

For program technical assistance, contact: Zachary Taylor, MD, MS, Project Officer, Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE., Atlanta, GA 30333. Telephone: 404–639–8126, e-mail: *ZTaylor@cdc.gov.*

For financial, grants management, or budget assistance, contact: Jesse Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2747, e-mail: *JRobertson@cdc.gov.*

Dated: May 21, 2004.

William P. Nichols,

Acting 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

Guide to Community Preventive Services (GCPS) Task Force

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 meeting:

NAME: Task Force on Community Preventive Services.

TIMES AND DATES: 8 a.m.–6:15 p.m., June 9, 2004. 8 a.m.–12:30 p.m., June 10, 2004.

PLACE: The Crowne Plaza Ravinia, 4355 Ashford Dunwoody Road, Atlanta, Georgia 30346–1521, telephone (770) 395–7700.

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

PURPOSE: The mission of the Task Force is to develop and publish a Guide to Community Preventive Services, which is based on the best available scientific evidence and current expertise regarding essential public health services and what works in the delivery of those services.

MATTERS TO BE DISCUSSED: Agenda items include: briefings on administrative information, options for handling insufficient evidence, and dissemination of Community Guide findings. The Task Force will also consider reviews of evidence and possible recommendations on school-based interventions for violence prevention, reducing structural barriers to cancer screening, folic acid fortification and supplementation, partner counseling and referral services for HIV prevention, and environmental and policy approaches to promoting physical activity.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON OR ADDITIONAL INFORMATION: Peter Briss, M.D., M.P.H., Chief, Community Guide Branch, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, CDC, 1600 Clifton Road, M/S E–90, Atlanta, Georgia, telephone (404) 498–6180.

Persons interested in reserving a space for this meeting should call (770) 498–6180 by close of business on June 7, 2004.

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