

Funding Opportunity Announcement (FOA) – New, Non-research, Domestic

Amendment I, dated 07-22-2014, is being done to add at the following information to this FOA:

- 1. Extended application due date: September 4, 2014*
- 2. Provide the link to the current national TB program objectives and performance targets for applicant reference.*
- 3. Include funding ranges for each program component.*
- 4. Enhance language clarity in the following FOA sections (revised language is in RED text): “CDC Project Description (Outcomes)”;* “Funding Strategy”; “Strategy 5: Program Evaluation”; “Collaboration (with organizations external to CDC)”;
- “Target Population (inclusion)”;* “Work Plan”; “CDC Program Support to Awardees”; “Project Narrative”; “Budget Narrative”; “Award Information”.
- 5. FOA Questions and Answers from the informational conference call with applicants (Attached at the end of the FOA)*

Tuberculosis Elimination and Laboratory Cooperative Agreement

CDC-RFA-PS15-1501

National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention



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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS15-1501. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.
A. Federal Agency Name:
Centers for Disease Control and Prevention (CDC)
B. Funding Opportunity Title:
Tuberculosis Elimination and Laboratory Cooperative Agreement (CoAg)
C. Announcement Type: New – Type 1:
This announcement is only for new, non-research, domestic activities supported by CDC. If research is proposed, the application will not be considered. Research for this purpose is defined at http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf .
D. Agency Funding Opportunity Number:
CDC-RFA-PS15-1501
E. Catalog of Federal Domestic Assistance (CFDA) Number:
93.116, Tuberculosis Elimination and Laboratory Cooperative Agreement
F. Dates:
1. Letter of Intent (LOI) Deadline: N/A
2. Application Deadline: September 4, 2014. Applications due 11:59 p.m. U.S. Eastern Daylight Time.
3. Informational conference call for potential applicants: The call in number for both calls is 1-866-880-0098 and the passcode is 4234566630#. Program call: July 10, 2014, 3p to 5p EDT, Leader: Glen Christie Laboratory call: July 14, 2014, 3p to 4p EDT, Leader: Angela Starks
G. Executive Summary:
1. Summary Paragraph:
The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year (FY) 2015 funds to implement funding opportunity announcement (FOA) CDC-RFA-PS15-1501 Tuberculosis (TB) Elimination and Laboratory Cooperative Agreement (CoAg). TB CoAg funds support TB Prevention and Control (P&C) activities, TB programs' Human Resources Development (HRD) activities, and Public Health Laboratory Strengthening activities according to formulas that reflect TB disease incidence, complexity of cases and program performance.
a. Eligible Applicants: Limited to 62 project areas, including 50 state public health agencies or their bona fide agents; the cities Los Angeles, CA; San Francisco, CA; San Diego, CA; Houston, TX; Chicago, IL; Detroit, MI; New York, NY; Philadelphia, PA; Baltimore, MD;

Washington, D.C.; and the territorial governments of Puerto Rico and U.S. Virgin Islands.
b. FOA Type: Cooperative agreement
c. Approximate Number of Awards: 62
d. Total Project Period Funding: \$385,601,610
e. Average One Year Award Amount: \$1,243,876
f. Number of Years of Award: 5 years
g. Approximate Date Awards Will be Announced: December 1, 2014
h. Cost Sharing and /or Matching Requirements: Cost sharing and/or matching funds are not required. Although matching is not required for this FOA, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background:

The Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination (DTBE) is the lead Federal Agency for TB prevention and control (P&C) funding, resource coordination, and development and promulgation of national strategies and policies. As such, DTBE is continuing a 30-year strategy of federal involvement in funding essential elements in TB programs through a Cooperative Agreement (CoAg). The primary responsibility for designing and carrying out TB P&C activities rests with state and local health departments, not the Federal Government.¹ This CoAg is intended to complement ongoing TB P&C and laboratory services and activities at the local and state level. It is not the intent of this CoAg to supplant, replace, or reduce state and local support for TB control activities and responsibilities (e.g., provision of medications, in-patient care, and health department facilities).

DTBE distributes TB CoAg funds to support TB P&C activities, Human Resource Development (HRD) activities and Public Health Laboratory Services based on data-driven funding formulas to align the funding with the changing TB epidemiology in the United States. The formula to support P&C and HRD activities was developed in collaboration with the National TB Controllers Association (NTCA) and has been gradually phased in over time. Starting in 2015, 100% of funds will be allocated according to the funding formula.

Laboratory funding will be determined for each jurisdiction according to a workload-based formula. Laboratory funds are directed at ensuring high-quality laboratory testing with rapid turn-around-time (TAT) and improved efficiency in laboratory testing algorithms.

¹ U.S. Congress, Office of Technology Assessment, *The Continuing Challenge of Tuberculosis*, OTA-H-574 (Washington, DC: U.S. Government Printing Office, September 1993); pp 12.

Certain populations are disproportionately affected by TB, such as persons with HIV infection or diabetes, persons experiencing homelessness, persons who are incarcerated, or persons who use illicit substances. The TB incidence rate among foreign-born persons in 2013 was approximately 12 times greater than the incidence rate among U.S.-born persons, and the percentage of TB cases occurring in foreign-born persons continues to increase, reaching 64.6% in 2013. Achieving TB elimination in the United States will involve focusing on persons in these risk groups.

Further priority should be focused on case clusters where genotype or field investigation information suggests recent transmission. For example, clusters involving homeless or incarcerated populations, or users of illicit substances, frequently involve recent transmission. Clusters with suspected recent transmission should be prioritized for intensified interventions to interrupt transmission.

a. Statutory Authorities:

This program is authorized under Section 317E of the Public Health Service Act, [42 U.S.C. Section 247b-6] as amended. The Catalog of Federal Domestic Assistance Number is 93.116.

b. Healthy People 2020:

This FOA addresses the Healthy People 2020 focus areas of TB P&C activities as well as rapid laboratory detection:

<http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>

c. Other National Public Health Priorities and Strategies:

This FOA also addresses strategic imperatives found in the National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases (STD), and Tuberculosis (TB) Prevention (NCHHSTP) overall goals for 2010–2015 related to the following: Prevention Through Healthcare; Program Collaboration and Service Integration (PCSI); Health Equity; Global Health Protection and Health Systems Strengthening; Partnerships; and Workforce Development and Capacity Building.

d. Relevant Work:

This FOA builds on the significant work of past TB P&C CoAgs, which were in large part responsible for the reversal of the 1985–1992 resurgence of TB in the United States. The resurgence was fueled by budget cuts, growing incidence of HIV infection, and the transmission of multidrug-resistant TB (MDR TB) in hospitals and other settings. These CoAgs helped ensure the downward incidence trends over the past 20 years, with the United States achieving the historic lowest incidence of TB in 2013.

In addition, this CoAg will continue to aid public health laboratories in implementing new methods and technologies as an integral component of TB control efforts. Furthermore CDC's support and guidance of CoAg recipients, representing health departments from states, territories, and several large cities, help to ensure that efforts to prevent and control the transmission of *Mycobacterium tuberculosis* in the United States will continue to be successful.

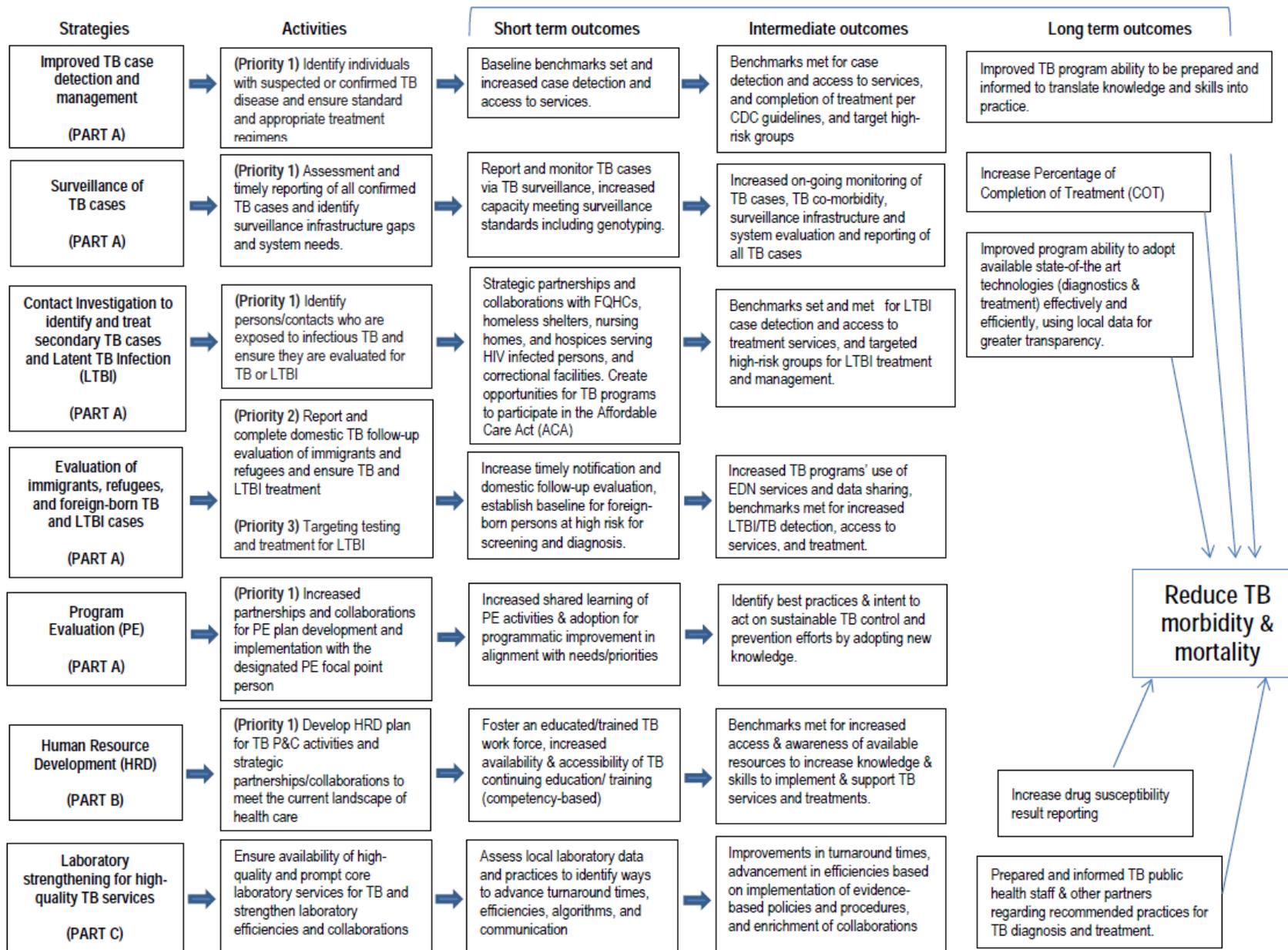
2. CDC Project Description

a. Approach:

Goal is to reduce morbidity and mortality caused by TB by

- Preventing transmission of M. tuberculosis from persons with infectious disease to uninfected persons, and
- Preventing persons from progressing from latent TB infection (LTBI) to TB disease.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm>

**Tuberculosis Elimination and Laboratory Logic Model:
Program Evaluation**



*Awardees expected to achieve all outcomes depicted in the logic model

<p>i. Problem Statement:</p>
<p>TB is an airborne disease and one of the world’s deadliest. In 2012, an estimated 8.6 million people worldwide developed TB disease, and 1.3 million died from TB.</p> <p>TB is a leading killer worldwide of people living with HIV, causing one quarter of all HIV deaths: http://www.who.int/mediacentre/factsheets/fs104/en/index.html Many people arrive in the United States annually from countries with high burdens of TB including immigrants, refugees, students, or travelers. Persons with Latent TB Infection (LTBI) provide a reservoir of people who may later develop active disease.</p> <p><i>M. tuberculosis</i> is a slow growing organism, which means that conventional laboratory test results can take weeks to months to confirm species identification and drug susceptibility. TB cases, while on the decline in most of the United States, can be complex with drug-resistant strains of TB. These cases require longer duration of treatment and these patients might remain infectious longer. Their infected contacts will require more complex preventive therapy. TB remains a challenging public health problem in the United States with over 9,000 cases in 2013. http://www.cdc.gov/tb/statistics/reports/2012/default.htm Rising costs of health care, shortages of medications and diagnostic materials, http://www.cdc.gov/mmwr/pdf/wk/mm6240.pdf (pages 1014-1015), and outbreaks with long-lasting impacts are all factors which add to the costs of containing and preventing TB in the United States. In 2007, direct costs, mostly covered by the public sector, averaged \$134,000 per MDR TB and \$430,000 per XDR TB patient; in comparison, estimated cost per non-MDR TB patient was \$17,000.²</p>
<p>ii. Purpose:</p>
<p>The purpose of the Tuberculosis (TB) Elimination Cooperative Agreement (CoAg) funds is to assist the current efforts of state, local, and territorial TB programs to prevent, control, and eventually eliminate TB in the United States. Financial assistance is provided to TB programs to augment current local contributions for TB prevention and control activities; developing human resources through improved training, education, communications, and information dissemination; and strengthening laboratory capacity to ensure that timely and reliable TB laboratory services be available to healthcare providers and TB controllers.</p>
<p>iii. Outcomes:</p>
<p>By the end of this 5-year project period, awardees are expected to have achieved all the short-term and intermediate outcomes in the logic model, as well as the following long-term</p>

² Marks SM, Flood J, Seaworth B, Hirsch-Moverman Y, Armstrong L, Mase S, et al. Treatment practices, outcomes, and costs of multidrug-resistant and extensively drug-resistant tuberculosis, United States, 2005–2007. *Emerg Infect Dis.* 2014 May. <http://dx.doi.org/10.3201/eid2005.131037>

outcomes: a) improved their program’s ability to be prepared and informed to translate knowledge and skills into practice, b) increase the proportion of completion of treatment, c) improved their ability to adopt available state-of-the-art technologies effectively and efficiently, using local data for greater transparency, d) increased drug susceptibility result reporting, and e) have prepared and informed staff and partners regarding recommended practices for TB diagnosis and treatment. These outcomes should be achieved for TB programs in alignment with current National TB Program Objectives. **These outcomes should be achieved for TB programs in alignment with current National TB Program Objectives and Performance Targets that can be found at <http://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>.**

iv. Funding Strategy:

CDC DTBE will use a funding strategy for all three components of the CoAg that has been built on years of experience and collaboration with multiple public health partners. DTBE distributes TB CoAg funds according to a case-based formula for P&C, HRD, and a workload-based funding formula for the laboratory. Furthermore, two performance indicators are included within the P&C formula: Completion of Therapy (COT) and Drug Susceptibility Testing (DST). Thus, the funding formula for P&C is divided into a “needs” component and a “performance” component, with funding allocated at 80% and 20% respectively. This strategy aligns the funding with the changing TB epidemiology in the United States.

The P&C formula was developed in collaboration with the National TB Controllers Association (NTCA) and the Laboratory formula was developed in collaboration with the Association of Public Health Laboratories (APHL). The funding formula has been gradually phased in over time, and starting in 2015, funding will be completely allocated according to the formula.

There may be situations when additional funds are required such as unexpected increases in cases, contacts, or persons with LTBI. These represent potential exceptions to the funding formula that could be addressed with other unique, ad hoc allocations needed to support emergency outbreak responses. To facilitate this, recipients should submit a “true needs” budget for both P&C and Laboratory components that anticipates the amount needed for operational costs, program improvement initiatives, and potential emergencies.

The following spreadsheet shows the anticipated 2015 funding ranges for the three tiers identified for P&C and HRD, as well as ranges for PH laboratory, as determined by the application of the current funding formula. This projection is based on availability of funds and subject to change if the overall funding level changes.

Anticipated FY2015 Funding Ranges by Tiers		
Tiers	TB Prevention & Control	Human Resource Development
Tier 1 (≤ 50 cases)	\$100,301.00 - \$318,095.00	\$17,500.00 - \$18,500.00
Tier 2 (51-500 cases)	\$446,469.00 - \$2,386,555.00	\$24,000.00 - \$25,000.00
Tier 3 (> 500 cases)	\$4,551,373.00 - \$8,306,370.00	\$41,000.00 - \$42,000.00

Anticipated FY2015 Funding Ranges by Workload	
Workload	Laboratory
(<1000 patients*)	\$35,000.00 - \$86,233.00
(1000-2500 patients*)	\$41,581.00 - \$199,886.00
(2501-5000 patients*)	\$116,895.00 - \$244,367.00
(>5000 patients*)	\$265,210.00 - \$598,074.00

* To determine laboratory tier, use the SUM of the number of individual patients for whom a clinical specimen was processed in 2013 PLUS the number of individual patients for whom a reference isolate was received in 2013. These values correspond to workload indicators #2 and #3 on page 23 of the FOA.

v. Strategies and Activities:

TB Prevention and Control (P&C)

This FOA adopts a priority-based approach for program activities in the P&C component. The included logic model (see page 6) identifies program activities under the priority-based approach that are aligned with defined strategies. It is understood that programs take a graduated approach in applying their TB P&C strategies according to their overall success of their activities. All programs are encouraged to employ all the strategies in the logic model in this FOA. Programs experiencing success with certain strategies should share best practices with other TB programs.

The three levels of priorities enumerate the activities that programs should accomplish based on the tier to which they are assigned. Jurisdictions are assigned to tiers based on the number of TB cases they report each year. The DTBE program consultant can be of assistance for establishing program priorities as needed.

Tier 1: Programs reporting ≤ 50 TB cases annually are expected at minimum to perform the activities outlined under Priority 1 before working on other program enhancements.

Tier 2: Programs reporting 51–500 TB cases annually are expected at minimum to perform the activities under Priorities 1 and 2.

Tier 3: Programs reporting > 500 TB cases annually are expected at minimum to implement the activities across all priority levels.

Table: Activities to be completed in order of priority

Priority 1 (Tiers 1, 2, and 3)	Priority 2 (Tiers 2 and 3)	Priority 3 (Tier3)
<ul style="list-style-type: none"> • Assess and report all confirmed TB cases, and conduct large outbreak surveillance and response • Identify individuals with suspected or confirmed TB • Ensure appropriate treatment and case management of persons with TB • Conduct case reviews at least monthly • Identify persons/contacts who are exposed to <i>M. tuberculosis</i> and ensure they are evaluated and treated for TB or LTBI if indicated • Conduct program evaluation (PE) initiatives for above activities • Ensure appropriate training, education, and other HRD activities • Ensure availability of high-quality and prompt core laboratory services for TB, and strengthen laboratory efficiencies and collaborations 	<ul style="list-style-type: none"> • Complete all activities from priority 1, as well as the following: • Conduct evaluation of immigrants and refugees with TB or LTBI • Conduct cohort review at least annually 	<ul style="list-style-type: none"> • Complete all activities from priorities 1 and 2, as well as the following: • Ensure target testing and treatment for LTBI • Conduct cohort reviews more frequently than annually

Strategy 1: Improved TB Case Detection and Management

To accomplish the priority 1 activity of identifying individuals with suspected or confirmed TB disease and ensure standard and appropriate treatment regimens, the following should be conducted:

- Ensure case management and treatment of persons with active TB through the use of adherence-promoting measures such as case review/cohort analysis, outreach staff who are culturally competent, extensive application of directly observed therapy (DOT), incentives, and enablers.
- 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/tb/topic/treatment/default.htm>

- Seek expert consultation for treatment of MDR TB and other complex cases from Regional Training and Medical Consultation Centers (RTMCCs), and seek consultation regarding laboratory results for molecular detection of drug resistance when needed:
<http://www.cdc.gov/tb/topic/laboratory/default.htm>
<http://www.cdc.gov/tb/topic/laboratory/rapidmoleculartesting/default.htm>
<http://www.cdc.gov/TB/education/rtmc/>
- Collaborate with HIV/AIDS programs to ensure that all newly diagnosed TB cases are tested for HIV and referred for HIV services if infected with HIV.
- Collaborate with partners at correctional facilities, homeless shelters, and substance abuse settings to ensure that all newly diagnosed TB cases are evaluated and treated for TB.
- Utilize, promote, and promulgate effective binational referral mechanisms for patients who may receive care along the U.S.-Mexico border or who may cross the border while taking treatment for TB. For more information, please see these links:
http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb/
<http://www.migrantclinician.org/services/network/tbnet.html>
- Partner with CDC Division of Global Migration and Quarantine (DGMQ) to support international and binational TB quarantine efforts.
- Establish a systematic process to evaluate case management activities routinely to ensure optimal program performance.
- 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 *M. tuberculosis*.

Strategy 2: Surveillance of TB Cases and Case Reporting

To accomplish the priority 1 task of timely assessment and reporting of all confirmed TB cases and identifying surveillance infrastructure gaps and system needs, the following should be conducted:

- Report complete data on all TB cases in the Report of Verified Case of Tuberculosis (RVCT). All RVCT data items should be filled out completely according to CDC instructions for the revised RVCT: <http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf>
- Complete RVCT follow-up 1 and 2 reports and submit to CDC as soon as those data are available.
- Ensure that at least one isolate from persons with culture-positive TB is submitted for genotyping, and that genotyping results are linked to surveillance data within 8 weeks of genotype results becoming available. This linking should generally be performed by state TB programs and accomplished by either of the following:
 - Using the TB Genotyping Information Management System (TB GIMS), an online data management and analysis application hosted by CDC; or
 - Entering the genotyping lab accession number in item #38 on the RVCT. Genotyping

records that are not linked to National TB Surveillance System (NTSS) records will not appear in TB GIMS reports and are not considered when TB GIMS issues alerts for possible outbreaks. Best practices for TB genotyping are available at

www.cdc.gov/tb/publications/factsheets/statistics/Genotyping_BestPractices.pdf

- Notify CDC when experiencing large outbreaks (≥ 10 related cases diagnosed in a 3-year period). Regardless of method of detection, programs should respond to large outbreaks and report response activities to CDC. Programs experiencing large outbreaks should report on their outbreak response, including methods of intervention (e.g., aggressive LTBI treatment programs for persons experiencing homelessness, intensified case-finding that focuses on locations in addition to traditional contacts), resource utilization, and updated epidemiologic data (e.g., case counts, contacts identified, contacts evaluated, contacts initiating LTBI treatment, contacts completing LTBI treatment).
- Enhance identification, reporting, and follow-up of persons with TB and with suspected TB 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 at risk for TB. TB programs 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 persons with TB and with suspected TB.
- Develop and implement surveillance activities to ensure complete, accurate, and timely reporting and counting of TB cases, and maintain a data system of verified TB cases. Timeliness includes electronic reporting via HL7 messaging of all verified TB cases to CDC on a monthly or at least quarterly basis.
- Provide HIV testing for all persons with TB disease at time of diagnosis.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm>
- Ensure data security and confidentiality guidelines for HIV/AIDS, Viral Hepatitis, STD, and TB Programs are followed.
<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>
- Report how each of the quality assurance (QA) components for TB surveillance data will be conducted. These components include case detection, data accuracy, data completeness, data timeliness, and data security and confidentiality.

Strategy 3: Contact Investigation

To accomplish the priority 1 activity of identifying persons/contacts who are exposed to infectious TB and ensure that they are evaluated for TB or LTBI, the following should be conducted:

- Ensure that contact investigation activities are initiated and completed promptly; including interviewing TB cases or utilizing location-based methods to identify contacts, evaluating contacts for LTBI and disease, and ensuring that infected contacts begin and complete an

appropriate course of treatment for LTBI.

- Assess reasons for cases with no contacts identified or a low number (≤ 3) contacts identified, delays in interviewing cases or evaluating contacts, low rates of completion of LTBI treatment, 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 investigation activities.
- Submit data from contact investigations in the Aggregate Reports for Tuberculosis Program Evaluation (ARPE): Follow-up and Treatment of Contacts to Tuberculosis Cases. Additionally, programs that have been using their own database for contact investigation data collection can continue for improved reporting on current and new program objectives.

Strategy 4: Evaluation of immigrants and refugees with TB or LTBI

This strategy involves the completion of two priority activities. The first is the priority 2 activity to report and complete domestic TB follow-up of immigrants and refugees, and ensure TB and LTBI treatment. The second is the priority 3 activity of targeted testing and treatment for LTBI. The following should be conducted:

- Ensure that immigrants and refugees classified as A, B1, or B2 are located promptly and evaluated and treated appropriately: <http://www.cdc.gov/immigrantrefugeehealth/>
Report domestic TB follow-up evaluation results of immigrants and refugees to ensure completion treatment of TB and LTBI to the Electronic Disease Notification (EDN) system: <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6207a1.htm>
<http://www.cdph.ca.gov/programs/tb/Documents/TBCB-CDC-EDN-TB-Follow-up-Guide-2011.pdf>
- Targeted testing and treatment of LTBI
 - Ensure that effective interventions are implemented to identify foreign-born and locally-determined high-risk populations for developing TB, and that they are evaluated and treated for TB and TB infection.
 - Establish partnerships with HIV, diabetes, and/or other non-communicable disease program staff (e.g., smoking, alcohol abuse) to promote testing for TB infection and referral for TB services among those with HIV, diabetes, or other behavioral risk factors which increase the risk of progressing from LTBI to TB disease.

<http://www.idf.org/diabetesatlas/5e/diabetes-and-tuberculosis>
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2945809/>

Strategy 5: Program Evaluation (PE)

This cross-cutting strategy is accomplished through increased partnerships and collaborations of PE plan development and implementation with the designated PE focal point.

PE examines achievement of program objectives in the context of other aspects of program performance or in the context in which it occurs.³ The purposes of PE are to 1) increase programmatic accountability in implementing priority based approaches depicted in the strategies from the logic model; 2) identify and overcome bottlenecks supported by timely analysis and feedback; and 3) continually improve program and clinical practices and performance. The PE focus is to identify and include opportunities to bridge the gaps between knowledge/learning and practices to improve program and clinical effectiveness.

The designated PE focal point will be responsible for the following:

- Serve as the point of contact in their respective jurisdiction for development and implementation of a program evaluation plan and activities specific to their TB program needs and improvements
- Share program evaluation experiences and lessons learned with stakeholders and beneficiaries
- Provide the cornerstone for building program evaluation capacity within the jurisdiction
- Work closely with TB program staff including DTBE program evaluation consultants
- **Engage in TB Program Evaluation PE Network (PEN) activities. This person should be an active participant in the TB PEN, and shall attend the TB PEN Conference.**

Note: The mission of TB PEN is to develop and strengthen the capacity of state and local TB programs to monitor and evaluate their programs and use findings to enhance the effectiveness of P&C activities.

³ U.S. Government Accountability Office (GAO). Performance measurement and evaluation: definitions and relationships. May 2005. GAO-05-739SP.

Strategy 6: Human Resource Development (HRD)

This strategy involves developing HRD plans for TB P&C activities and strategic partnerships /collaboration to meet the current knowledge and skills needed by health care providers. This is accomplished through the following:

- Continue to ensure that someone is designated as the focal point for training and education. This person should be (or become) a member in the Tuberculosis Education and Training Network (TB ETN). Areas of responsibility for TB education and training focal points will include the following:
 - Serve as primary contact in their respective TB program for DTBE and RTMCC education and training activities, including needs assessments, capacity building, and resource development/sharing
 - Ensure development and implementation of an annual Training and HRD plan specific to their TB program
 - Provide annual update of progress-to-date on HRD plan activities
 - Coordinate development and implementation of subsequent annual HRD plans
 - The training and education focal point shall attend the focal point meeting and TB ETN conference.
- Develop an annual training and Human Resource Development (HRD) 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 HRD 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, viral hepatitis, and STD.
 - Target other health care providers or organizations serving high-risk populations.

Strategy 7: Public Health Laboratory Strengthening

This strategy ensures the availability of high quality and prompt core laboratory services for TB and strengthening laboratory efficiencies and collaborations. This is accomplished through the following:

- Public health laboratories should ensure availability of reliable, timely laboratory services, and use recommended conventional and molecular methodologies for the isolation of, identification of, and susceptibility testing for *M. tuberculosis* complex (MTBC) appropriate to the individual laboratory's workload and experience (e.g., refer to Clinical and Laboratory Standards Institute (CLSI) documents M24-A: Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard and M48-A Laboratory Detection and Identification of Mycobacteria).
- State and local public health laboratory strategies and activities should include the following: Develop and implement plans to meet CDC recommended turn-around times

(TATs) and the Healthy People 2020 goal. Establish laboratory specific outcomes and take corrective actions as needed to improve or sustain TATs based on national recommendations.

- Based on level of service and workload, programs should develop and implement plans aimed at ensuring continued access to core laboratory services including in-house or referred access to NAATs or other rapid tests for detection of MTBC directly from clinical specimens.
 - Public health laboratories that process fewer than 20 specimens per week (the minimum level of activity to maintain proficiency) should provide a plan to maintain proficiency, or consider collaboration with another laboratory.
 - Public health laboratories that perform first-line drug susceptibility testing for < 50 patient isolates/year should refer these isolates to a partner laboratory.
- Ensure that at least one isolate from all persons with culture-confirmed TB is submitted for genotyping in a timely manner as established by mutual agreement with TB program. Best practices for TB genotyping are available at www.cdc.gov/tb/publications/factsheets/statistics/Genotyping_BestPractices.pdf
- Monitor and assess local data and use these data to guide decisions regarding testing algorithms, services, and business practices for gained efficiencies.
- Collaborate with partners to ensure optimal use of laboratory services and timely flow of information.
- Promote establishment of laboratory as an integrated co-equal partner within the TB program, frequently providing subject matter expertise. In addition, participant laboratories should establish and maintain a cooperative relationship with CDC laboratory consultants.

1. Collaborations

a. With CDC funded programs:

Applicants should develop a plan and timeline for working with other relevant CDC-funded programs in their jurisdiction that are targeting the same populations. Collaborations should also exist between states and CDC funded Regional Training and Medical Consultation Centers (RTMCCs): <http://www.cdc.gov/TB/education/rtmc/> Other partners that TB programs should collaborate with include those funded by 1) the Division of Viral Hepatitis, 2) the Division of Sexually Transmitted Diseases Prevention, 3) the Division of HIV/AIDS Prevention, 4) the Division of Diabetes Translation, 5) Division of Global Migration and Quarantine, and 6) the Immunization Services Division. The expectation of the collaboration is to improve technical and program guidance, strategies and relevant activities, and PE plans and efforts.

To facilitate program collaboration and service integration, funds can be used to hire a part-time Program Collaboration and Service Integration (PCSI) coordinator and PCSI data analyst who can be placed in the organizational structure so they have the authority to influence PCSI activities.

b. With organizations external to CDC:

Collaborating partners should include, but are not limited to the following organizations, agencies and groups within the geographic catchment area: private providers; medical and

nursing schools and related teaching hospitals, public health schools and associations; regional TB controller associations; TB advisory councils; U.S. panel physicians and civil surgeons (as guided by CDC); STD/HIV Prevention and Training Centers; Viral Hepatitis Education and Training Centers; Health Resources and Services Administration (HRSA) primary care centers; AIDS Education and Training Centers; Substance Abuse and Mental Health Services Administration (SAMSHA); and Addiction Technology Transfer Centers.

Applicants are required to partner with the following organizations external to health departments that have access to target populations:

- Each grantee will designate at least one liaison for locally determined high-risk populations. Liaisons will be responsible for ensuring a process is in place to foster collaborations between programs and agencies (i.e., correctional facilities, homeless shelters, etc.) and should provide brief summary reports in the annual progress report (APR) and final progress reports of activities that address TB control priorities involving these populations.
- Each grantee will collaborate with HIV/AIDS programs, community planning groups, HIV care consortiums, and other local groups that influence funding and programmatic activities to ensure that all newly diagnosed TB cases are tested for HIV and referred to STD and hepatitis services if found to be HIV positive. Efforts should be made to offer rapid HIV testing to patients in TB clinics.

In addition, applicants are strongly recommended to collaborate with other external organizations:

- Grantees are encouraged to seek collaboration between health departments and Medicaid agencies at Federal and State levels and to collaborate with community health centers (CHCs), including federally qualified health centers (FQHCs), and schools of Public Health, to integrate primary care and public health efforts:
<http://www.cdc.gov/nchhstp/preventionthroughhealthcare/docs/PreventionthroughHealthCare-010512.pdf>
- Grantees are encouraged to communicate with Health Care for the Homeless Council as potential partners to address TB control among the homeless:
<http://www.nhchc.org/resources/clinical/diseases-and-conditions/tuberculosis/>
- Grantees are encouraged to collaborate on trainings with HIV/AIDS, STD, and viral hepatitis training partners and to integrate disease content as appropriate in courses as outlined by the NCHHSTP's Program Collaboration and Service Integration (PCSI) Strategy section earlier in the announcement. Go to the following link for more information: <http://www.cdc.gov/nchhstp/programintegration/Default.htm>
http://www.cdc.gov/nchhstp/programintegration/docs/207181-C_NCHHSTP_PCSI%20WhitePaper-508c.pdf
- Grantees are encouraged to enroll in Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program which would enable them to purchase TB medication at reduced drug prices. An organization that enrolls in the 340B Program must comply with all 340B Program requirements and will be subject to audit at any time regarding

340B Program compliance. 340B Program requirements can be found at www.hrsa.gov/opa/.

Memoranda of Understanding (MOUs)/ Memoranda of Agreement (MOAs) are not required for the FOA but are strongly recommended if the project area determines that formalization of collaboration is needed with an organization. If a project area chooses to develop MOUs/MOAs, they can be submitted as attachments.

2. Target Populations:

This CoAg is set up to provide funding for state, local, and territorial programs to prevent, control, and ultimately eliminate TB in the United States in the following target populations:

- All persons with TB disease
- Foreign-born persons residing in, or traveling to, the United States
- Racial and ethnic minority populations
- Persons living with HIV and/or diabetes mellitus
- Persons working or residing in congregate settings (correctional facilities, homeless shelters)

Inclusion:

Among the target populations identified above, applicants should strive to be inclusive of people with limited health literacy, non-English speaking or limited English speaking populations, or other vulnerable people in the target population who may otherwise be missed by the program. Applicants should propose specific strategies to reach these populations.

Health Equity: TB disproportionately affects persons based on race/ethnicity, and country of origin and persons who have limited access to health care and services. TB mission driven priority areas are meant to address such disparities. There are roadmaps from CDC, NCHHSTP, and DTBE to guide our strategic efforts or interventions to address such health disparities. Additionally, the Healthy People 2020, the National Prevention Strategies, and the HHS Action Plan to reduce and Eliminate Health Disparities call for enhancing collaboration and coordination of health disparities activities.

Each program should initiate and maintain activities to address health equity issues. Applicants should outline how they will develop program strategies to address this issue.

b. Evaluation and Performance Measurement:

i. CDC Evaluation and Performance Measurement Strategy:

CDC expects to document the programs', patients', and providers' needs, values, and perspectives, and the documentation is an integral step in the process toward developing evidence-based program practices and performance.

CDC/DTBE PE staff will provide guidance in designing, implementation, and evaluation of PE plans in collaboration with TB control program staff and PE focal point persons. Both process evaluation measures (to determine whether information and services are being adequately delivered) and outcome evaluation measures (to determine whether information and services delivered are having desired impact), will be used and developed, consistent with the logic

model and activities under the applicable priority level presented earlier.

Grantees will have autonomy in selecting PE focus areas representing some or all program strategies, incorporating the priority level activities and relevant outcomes. Both types of measures, with current and timely data utilization, will be used to increase accountability and continuously improve program practices and performance.

CDC strategies for PE include performance measures required for all priority level activities, and support grantee specific strategies, activities, and outcomes. Programs should consider the variety of metrics and available systems capable of supporting the overarching program goals and the designated short- and intermediate-term outcomes. They must weigh the benefits and the burdens of data collection against the quality of data.

The following PE specific questions will span measures of grantees' activities and measures of outcomes:

1. What activities were conducted to achieve the program outcomes relevant to specific program priority of choice and program strategy?
2. To what extent were all the proposed activities implemented?
3. What deliverables were produced as a result of the program activities conducted?
4. To what extent are the specific information needs of patients, providers, and program met?
5. To what extent is empirical data collection in diverse settings and for target populations able to define the economic and epidemiological context of TB control and prevention?
6. Were the proposed and/defined outcomes achieved (outlined in the National TB Program Objectives)?
7. Were collaboration and partnerships for meaningful cooperation and achievement of evidence-based strategies and interventions established and maintained?
8. Were potential actions/interventions based on current knowledge of diagnostic and treatment policies, and products were translated into practices?
9. To what extent were information and other outputs produced from the PE activities applied to target populations?

Performance measures will address both formative (process) and impact outcomes with a minimum of annual measures. Whenever applicable, new objectives and/or benchmarks that apply to high-risk populations or settings (care and service providers, RTMCCs, and facilities outside of the TB control program) must be included. Separate performance and outcome measures may need to be developed. For example, if a program planned to address the needs and services of homeless TB patients and/or conduct an outbreak investigation, descriptors need to be assessed to document who are the target populations, and evaluation questions need to be tailored to suit the specific goals for this population.

ii. Applicant Evaluation and Performance Measurement Plan:

Applicants must provide an initial evaluation and performance measurement plan to show how they will identify progress in implementing activities in their program strategies and achieve their outcomes and National TB Program Objectives (**maximum 5 pages**).

PE is carefully collecting information that can be used to facilitate necessary decision-making about a program. Applicants will develop and submit an evaluation plan. The plan should include program priorities, scope and nature of evaluation, evaluation questions, data needs, data sources, data collection, data analysis, timeline, roles of various stakeholders, expectations for reporting and sharing results, and anticipated use of results. Outcome measurements should incorporate National TB Program Objectives in the proposed work plan. In this section, the applicant will outline and refine actions needed to accomplish these performance measures or objectives that inspire confidence among partners and stakeholders, and add details of any additional evaluation to be completed.

Part II, section D (Application and Submission Information) of the FOA identifies CDC's general expectations of what evaluation and performance measurement plans must include. Including the following in the plan will also meet the expectations under Part II, section D.

- Describe how key focus areas or strategies will be identified and program stakeholders will be engaged in an evaluation plan development and implementation processes.
- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data that address patients, providers, health systems, and economic factors of TB care and management.
- Describe how evaluation findings will be shared among TB stakeholders for increased programmatic accountability, awareness, and engagement.
- Describe how evaluation and performance measurement will contribute to development of evidence-based practices and outreach programs that demonstrate value of TB control program efforts (e.g., impact on improving public health outcomes, cost-effectiveness, or cost-benefit).
- Describe how target populations (foreign-born persons, racial and ethnic groups) and congregate settings (homeless shelters, correctional facilities, places of worship, community health centers (CHCs), FQHCs, and private providers) will be included in the evaluation and performance measurements.
- Describe the engagement and functional roles of the designated PE focal point persons for developing and implementing evaluation and performance measurement plan.
- Describe what measures will be used to reach target populations in their respective settings.

Cohort Reviews

Cohort review can be part of applicant evaluation and performance measurement plan. The cohort review is a useful tool for ensuring accountability, informing and educating program staff about protocols and national objectives, and improving case management and prevention. To improve TB case management, program accountability, and feedback, programs should continue with case reviews as usual. Cohort reviews should be implemented based on the guidance provided by CDC DTBE. Additional information on conducting cohort reviews is also published in the CDC document, "Understanding the TB Cohort Review Process: Instruction Guide" accessible online at <http://www.cdc.gov/tb/education/cohort.htm>.

c. Organizational Capacity of Awardees to Execute the Approach:

It is expected that applicants should have the organizational capacity to develop, implement, and manage the work necessary for a TB control program and demonstrate their ability to execute their strategies, activities, and meet stated outcomes successfully.

Grantees should succinctly describe the physical structure of their state or local TB program(s) that will be in receipt of these cooperative agreement funds. This should include infrastructure, workforce competence, data systems, and electronic information systems to implement the activities. Each program must provide evidence of adequate program management, planning and development of policy, performance measurement, workforce development and training, and be fully capable to manage the required priority driven activities.

Grantees need to demonstrate briefly the capacity to manage persons who have suspected or active TB. This includes clinical care with appropriate medications, medical consultative services, infection control and coordination with other health-care providers. Grantees should confirm their ability to provide or refer TB patients for inpatient care and confinement if required. Programs should discuss their diagnostic methods for case finding and contact investigation, including laboratory and chest radiographic services. Grantees should describe their ability for managing persons infected with TB but without disease. Grantees should confirm their TB case reporting process including appropriate laws and regulations to support TB control activities, surveillance, and TB registry. Programs should describe their data collection and analysis. Programs should demonstrate adequate protection of confidentiality. Overall, programs should develop and provide a work plan and implementation plan with elements supporting the scope of their activities in relationship to TB control program strategies and target populations.⁴

d. Work Plan:

Prevention and Control (P&C)

The work plan should be high-level that covers the duration of the project, with more detail for the first of the project period. The work plan must, at a minimum, include the following:

- Priority level to be used for the project period and its alignment with the program strategies.
- Activities that are aligned with the selected priority level strategies to achieve stated outcomes with emphasis on the first year of the project period.
- Discussion of how the program will use information gathering, monitoring, analysis, and dissemination to address program priority activities.
- Explanation of how to support health equity approach in program services and activities including whether a PCSI model is utilized.

⁴ [Essential Components of a Tuberculosis Prevention and Control Program](#) (ACET) *MMWR* 1995; 44 (No. RR-11)

- Plan for data collecting, analyzing, and reporting of health equity approaches that have greatest impact on reducing health disparities.
- Description of P&C efforts among high-risk populations (foreign-born persons, persons residing in or working in congregate settings, such as correctional facilities, homeless shelters, and others).
- Administration and assessment process to ensure successful implementation and quality assurance.
- Staff and administrative roles and functions to support implementation of the FOA.
- Monitoring and evaluation plan for milestones accomplishing during the project period.

Sample Format for Developing Evaluation Plan (Maximum limit - 5 pages)

Review the following for developing a TB Program Evaluation Plan:

<http://www.cdc.gov/tb/programs/Evaluation/guide.htm>

- A. Purpose of the evaluation: Provide a clearly defined focus area with 1–3 goals, and state the purpose of the evaluation. (What does the program wish to learn/measure?) Clearly define objectives with specific actions that are needed to implement each goal. Objectives should be “SMART”: Specific, Measurable, Achievable, Realistic, and Time-bound. (What does the program want to do? Who will do how much of what by when?)
- B. Activities: Specify measures that support each objective. One objective may have multiple activities.
- C. Measures of activities: Specify indicators/criteria for success/failure in each activity.

Activities related to each objective	Types of data needed and data sources	Methods of assessment and time-line	Who is responsible for collecting data and analysis	Indicators (each activity may include multiple indicators)
1.1				
1.2				
1.3				
1.4				
1.5				

- D. Outcomes/ Impact: Focus on success linked with each activity including examples of success of objectives being met.

The CDC guiding standards for effective evaluation include:

- 1) Utility – does the information collected addresses the purpose and meet the needs of the intended audience?
- 2) Feasibility - are the evaluation goals, objectives, and activities realistic and practical in scope?
- 3) Propriety - does the evaluation account for ethical considerations?

4) Accuracy - will the results be valid and reliable?

Human Resource Development (HRD)

Training and HRD plan

The work plan must include an annual training and HRD plan that describes how activities will be executed to achieve the objectives identified under the “Strategies and Activities” in section A of the FOA.

Focal Point Designation

Grantees should continue to ensure that someone is designated to serve as a focal point for education and training within the TB program. This person should be (or become) an active participant in TB ETN. Areas of Responsibility for TB Education and Training Focal Points:

- Serve as primary contact in their respective TB program for DTBE and RTMCC education and training activities, including needs assessment, capacity building, and resource development/sharing
- Ensure development and implementation of an annual Training and HRD Plan specific to the TB program
- Provide annual update of progress-to-date on HRD plan activities
- Coordinate development and implementation of subsequent annual HRD plans
- Provide a line item budget for use of HRD funds

Please include a line-item budget to specify how CoAg funds will be used to achieve your program-specific HRD objectives and activities as stated in this document; seek guidance from your program consultant as needed.

Public Health Laboratory Strengthening

The applicant work plan for the Laboratory Component should include the following information and address Laboratory Elements 1, 2, and 3 as described below.

Provide an organizational chart of personnel performing laboratory testing for TB. Include a designated laboratory contact with contact information. Provide a brief description of the methods used in the laboratory, including those for specimen processing, direct detection, acid-fast bacilli (AFB) smear, culture, identification, and drug-susceptibility testing (DST) as well as a brief overview of testing algorithm. The concise description should include information on overall flow of specimens in the laboratory, how testing is reflected, referral practices, reporting protocols, electronic test ordering and reporting, and number of days per week testing is performed.

Laboratory Element 1: Ensure availability of high-quality and prompt core laboratory services for TB. All laboratories, regardless of volume, should describe anticipated outcomes and the specific strategies and activities for achieving these outcomes based on your laboratory-specific baseline for each indicator, and describe annual, incremental goals for improving turnaround time (TAT).

Laboratory-specific benchmarks should be established in an effort to meet or exceed national benchmarks. If currently meeting national benchmarks, focus activities on continued

improvement or sustained efforts. Describe any potential obstacles to meeting outcomes. Application may include plans to increase access to molecular testing in-line with local and national guidelines as well as plans for referral (e.g., first-line DST).

In tabular form, report the laboratory's data for each of the following workload and TAT indicators for the previous calendar year and year-to-date (January–June). These data should reflect testing for your jurisdiction only. (Refer to Glossary for an explanation of laboratory terms.)

- 1) Total number of clinical specimens that were processed for smear and culture. Do not include isolates referred from another laboratory.
- 2) Number of individual patients for whom a clinical specimen was processed for smear and culture
 - a. Of these, report the number of individual patients for whom at least one culture was positive for *M. tuberculosis* complex (MTBC).
 - b. Of these individuals positive for MTBC by culture, how many individual patients were initially positive by nucleic acid amplification testing (NAAT) of a clinical specimen in your laboratory? Note: This number should not include specimens referred for NAAT only (i.e., no culture performed in your laboratory). (Allows assessment of Healthy People 2020 goal)
- 3) Number of individual patients for whom a reference isolate was received to rule out or confirm the identification of MTBC. This should not include known nontuberculous mycobacteria.
 - a. Of these, report the number of individual patients that had at least one reference isolate identified as MTBC.
- 4) Number of individual patients for whom growth-based MTBC first-line DST was performed and/or, if was not performed in-house, for whom an isolate was referred to another laboratory for DST.
- 5) Number of individual patients for whom a clinical specimen or processed referred sediment was tested directly with a NAAT. (This includes testing performed in-house and referred testing.) This does not refer to rapid species identification tests performed on isolates (e.g., ACCUPROBE).
 - a. Of these, report the number of individual patients for whom a NAAT result was positive for MTBC. Note: For labs that accept referred specimens or sediments for NAAT-only, this number may be higher than data reported for 2b above.
- 6) Number of individual patients for whom the laboratory referred an isolate of MTBC for genotyping.
- 7) If applicable, provide the total number of interferon gamma release assays (IGRA) performed by your public health laboratory.

Report the calculated TAT for each recommendation as described below. Calculations should include weekends and holidays. Current performance targets can be found at <http://www.cdc.gov/od/oc/ohrt/tb-cooperative-agreement.aspx>

- Promote rapid delivery of specimens to the laboratory. Benchmark is receipt within 1 day of specimen collection. Report cumulative percent received within 1, 2, and 3 calendar days.
- Use fluorescent acid-fast staining and promptly transmit results by phone, FAX, or electronically. Benchmark is report within 1 day from receipt of specimen. Report cumulative percent transmitted within 1, 2, and 3 calendar days.
- Identify growth as acid-fast and use rapid methods to identify and report isolates as MTBC as soon as possible. Benchmark is report within 14–21 days from receipt of specimen. Report percent of MTBC isolates identified from initial diagnostic specimens identified within 21 calendar days.
- Determine the susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report results promptly. Benchmark is report within 17 days from identification of MTBC from culture. Report percent rifampin results reported for initial diagnostic specimens within 17 days of identification of MTBC from culture.
- Healthy People 2020 - Reduce the average time for a laboratory to confirm and report tuberculosis cases using NAAT. Healthy People 2020 goal is 2 days from receipt of clinical specimen for 77% of cases that are later culture confirmed. Of those identified as MTBC by culture, report the number of individual patients for whom a laboratory report of MTBC (i.e., positive NAAT or other positive direct detection method) was provided within 48 hours of clinical specimen receipt.

Volume Considerations for Addressing Laboratory Elements 2 and 3

Laboratories receiving < 2,000 clinical specimens each year should provide at least one measureable outcome for both components 2 and 3 as described below. Those laboratories receiving 2001–6,000 clinical specimens each year should provide at least two measurable outcomes, and those receiving > 6,000 clinical specimens each year should provide at least three measurable outcomes for each element 2 and 3.

Laboratory Element 2: Promote continual advancement of laboratory efficiency and quality assurance through use of local data. Set measurable outcomes specific for your laboratory volume and services. Specific strategies and activities to include in evaluation plans should be described and progress updated in all subsequent progress reports. As an example, laboratories might consider assessing testing algorithms and workload trends for potential redundancies, sources of delay, and efficient use of CDC or reference laboratory services.

Progress and evaluation may include an overview of any written policies to eliminate redundant testing. Additionally, applicants might examine business practices (e.g., electronic test ordering and reporting, cost recovery, referral systems, or data management) for process improvements. Laboratories may also consider use of the Association of Public Health Laboratories (APHL) tool, “*Mycobacterium tuberculosis: Assessing your laboratory*” as another means to examine local practices to potentially identify areas for improvements:

<http://www.aphl.org/aphlprograms/infectious/tuberculosis/Pages/TB-Self-Assessment-Tool.aspx>

It is anticipated that laboratories will implement process improvements during the 5-year project period. Gained efficiencies due to changes in practices should be monitored and documented.

Laboratory Element 3: Collaborate with partners (e.g., healthcare providers, TB control, and laboratory network) to ensure optimal use of laboratory services and timely flow of information. Set measurable outcomes appropriate for your laboratory volume and level of service. Describe strategies and activities to achieve outcomes and how progress will be evaluated. As an example, laboratories might initiate plans for educational opportunities/consultation for TB control and laboratory network, find opportunities to integrate evidence-based local practices with broader public health laboratory system and national strategies, and collaborate with TB control to improve awareness and understanding of laboratory services (e.g., development of specimen collection guidelines or promotion of laboratory services including NAAT). Evaluable feedback from both the laboratory, TB control, and other partners should be included as part of future reports to assess progress.

e. CDC Monitoring and Accountability Approach:

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). The HHS Awarding Agency Grants Administration Manual (AAGAM)* specifies the following HHS expectations for post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Insuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award and in concert with programs' needs and capacity
- Ensuring that awardees are performing at a sufficient level to achieve objectives within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.

These may include monitoring and reporting activities as outlined in Chapter 2.01.101 of the HHS AAGAM* that assists grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

DTBE specific monitoring and accountability approaches include the following activities:

1. Providing assistance to grantees in tracking and evaluating their progress toward reaching the proposed priority level activities and National TB Program Objectives.
2. Conducting conference calls with TB program staff and DTBE program consultant as well

as other relevant project personnel annually and/or as needed to assist in successful implementation of proposed activities.

3. Encouraging participation in webinars and awardee meetings and/or yearly reporting on successful program implementation for TB notes article.
4. Ensuring follow-up discussion of the feedback with appropriate program staff and DTBE stakeholders, including program, PE, and laboratory consultants within a given time line (e.g., 30 days).

*Beginning 10/01/2014, AAGAM will be replaced with GPAM.

f. CDC Program Support to Awardees:

Prevention and Control (P&C)

In a CoAg, CDC staff members are substantially involved in the program activities above and beyond routine grant monitoring during the project period.

CDC activities for this component are as follows:

- Providing guidance and coordination to improve the quality and effectiveness of work plans, PE strategies, and collaborative activities with other services and organizations (e.g., RTMCCs, private providers, community health centers [CHCs], federally qualified health centers [FQHCs]).
- **Providing consultation to programs through the DTBE Health Equity Workgroup on initiating and maintaining activities to address health equity issues.**
- Providing programmatic consultation and technical assistance in the development and implementation of new diagnostics and treatment services pertaining to TB control and prevention and to expand the reach of the population served.
- Supporting and facilitating activities relevant to PCSI and Health Equity as well as services outside the TB control program, such as, FQHC, CHC, RTMCC, and HIV.
- Providing technical assistance and consultation for empirical data collection in diverse settings to better define economic and epidemiologic context of TB control.
- Providing technical assistance to identify and notify areas about large outbreaks.
- Following up with programs to collect standardized public health information for clustered and non-genotyped cases and assess need for supplemental assistance.
- Collaborating with TB Program Evaluation Network (TB PEN) Steering Committee to incorporating any emerging, promising, and/or best practices to increase transparency, accountability, and adaption of these practices.
- Providing CDC or other subject matter expertise, technical assistance to assist awardee in areas requested such as surveillance, information technology, informatics, PE, program science approaches to strategy implementation, community engagement, and collaboration to advance program activities to achieve outcomes.
- Supporting and collaborating to compile and publish accomplishments, performance measures, and lessons learned during the project period.

Human Resource Development

CDC activities for this program are as follows:

- Providing technical assistance as needed in assessing and prioritizing training and education

needs and in planning, implementing, and evaluating training and education activities.

- Providing technical assistance as needed in developing a program specific Training and Human Resource Development Plan; assistance can be provided in-person at the focal point meeting at the bi-annual TB ETN conference or via consultation with DTBE after award of funds.
- Conducting a focal point meeting at the bi-annual TB ETN/TB PEN conference.
- Directing RTMCCs to coordinate planned regional on-site training courses in conjunction with designated focal points, and provide technical assistance as needed for development of program specific training activities.

Public Health Laboratory Strengthening

CDC activities for this program are as follows:

- Contributing to the improvement of public health laboratory performance by providing technical assistance through site visits and telephone consultations.
- Identifying training needs and collaborate with partners in the development of courses, webinars, workshops, and training materials for distribution to public health laboratories.
- Providing consultation for the development and implementation of laboratory performance indicators and data analysis methods for laboratory internal quality assurance programs.
- Assisting in the development and dissemination of best practice guidelines and recommendations for the implementation of cost-effective testing algorithms.
- Supporting laboratory performance evaluation by providing a biennial aggregate report of TATs and performance measures from laboratories receiving funding assistance and feedback on individual laboratory performance.

B. Award Information
1. Type of Award: Cooperative Agreement (CoAg) CDC’s substantial involvement in this program appears in the CDC Program Support to Awardees section.
2. Award Mechanism: U52 – Cooperative Agreement for Tuberculosis Control
3. Fiscal Year (FY): 2015
4. Approximate Total Fiscal Year Funding: \$77,120,323
5. Approximate Total Project Period Funding: \$385,601,610
6. Total Project Period Length: 5 years
7. Approximate Number of Awards: 62
8. Approximate Average Award: Total for 5 years is \$6,219,380
9. Floor of Individual Award Range: \$118,301 (This amount is subject to the availability of funds.)
10. Ceiling of Individual Award Range: \$8,304,252 (This amount is subject to the availability of funds.)

<p>11. Anticipated Award Date: December 1, 2014</p>
<p>12. Budget Period Length: 12 months</p> <p>Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the “Notice of Award.” This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).</p> <p>*Beginning FY 14, AAGAM will be replaced with GPAM.</p>
<p>13. Direct Assistance: Direct Assistance (DA) is available through this FOA.</p> <p>An official state, tribal nation, local or territorial government applicant may request that CDC provide DA in the form of federal personnel as a part of the grant awarded through this FOA. If the applicant’s request for DA is approved as a part of the award, CDC may reduce the funding amount provided directly to your jurisdiction as a part of your award. The amount by which the award is reduced will be used to provide DA; the funding shall be deemed part of the award and as having been paid to you, the awardee.</p> <p>DTBE may provide DA based on need and national strategic priorities. Applicants should submit a position description, organizational chart, and a letter of request. Pre-consultation with a DTBE program consultant is recommended. CDC also sponsors a Public Health Associate Program (PHAP) through the Office for State, Tribal, Local and Territorial Support (OSTLTS). Recipients of this CoAg are eligible to apply as host sites for PHAP fellows on an annual basis. Please see http://www.cdc.gov/phap/.</p>

<p>C. Eligibility Information</p>
<p>1. Eligible Applicants:</p> <p>Government Organizations:</p> <ul style="list-style-type: none"> • State or their bona fide agents (includes the District of Columbia) • Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico and the Virgin Islands • Political subdivision of States (including the cities of Los Angeles, CA; San Francisco, CA; San Diego, CA; Houston, TX; Chicago, IL; Detroit, MI; New York City, NY; Philadelphia, PA; Baltimore, MD) or their bona fide agents, and in consultation with their state government.
<p>2. Special Eligibility Requirements: N/A</p>
<p>3. Justification for Less than Maximum Competition:</p> <p>Eligible applicants that can apply for this funding opportunity are listed below: P&C - Eligible applicants are the 62 official state, territorial, and highest incidence city/district public health agencies which includes 50 states, 9 major U.S. cities (New York City, Houston, Detroit, Baltimore, San Francisco, San Diego, Philadelphia, Chicago, Los Angeles), the District of</p>

Columbia and two U.S. Territories (Puerto Rico, U.S. Virgin Islands) that are current recipients of project grant funds under CDC-RFA-PS10-1005, Tuberculosis Elimination and Laboratory for TB prevention, control, and elimination. These applicants have the necessary infrastructure in place to perform the activities required and have the experience needed to successfully complete the required functions.

TB Public Health Laboratory Strengthening - Of the 62 eligible applicants for support of P&C activities, 58 have eligible public health laboratories with the necessary laboratory infrastructure in place to perform the activities required and have the experience needed to successfully complete the required functions. These 58 eligible applicants include 50 states, 6 major cities (New York City, Houston, San Francisco, San Diego, Philadelphia, and Los Angeles), the District of Columbia, and Puerto Rico that are current recipients of project grant funds for TB prevention, control, and elimination.

The Tuberculosis Elimination and Laboratory CoAg has been in existence since 1983 to assist states, territories, and designated big cities in the prevention, control, and elimination of TB.

The eligibility should be limited to these areas based on the following reasons:

1. **Maintaining the TB control infrastructure** - As stated in the Institute of Medicine report, in an era of declining resources, it is of utmost importance to maintain the existing public health infrastructure for prevention, control and elimination of TB. In order to maintain the consistency of funding as well as the TB control infrastructure currently supported through federal TB CoAg funds, the eligibility is limited to the currently funded 62 project areas. Discontinuation of funds to these areas would result in decay of the TB control infrastructure and can risk the resurgence of TB in these areas.
2. **Consistency of distribution of CoAg funds** - Since FY 2005, Division of Tuberculosis Elimination (DTBE) has been gradually redistributing TB CoAg funds based on a data-driven funding formula. This has been done to align the funding with the changing TB epidemiology in the United States. The formula was developed in collaboration with the National TB Controllers Association (NTCA). CDC redistributed 20% of funds annually through FY 2007 based on 5-year averages of selected data factors, with an increase to 35% in FY 2008 with 65% as legacy funding. The funding formula was revised and updated for FY 2010 and the redistribution of funds beginning in 2015 will be 100% allocation of funds via the variable funding component of the formula. Consistency in project areas is important; otherwise, the funding redistribution amounts will not be consistent to support the changing epidemiologic needs for control and elimination of TB.

4. Cost Sharing or Matching:

Although matching is not required for this FOA, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort:

Maintenance of effort is not required for this program.

D. Application and Submission Information

Additional materials that may be helpful to applicants:

<http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.pdf>

1. **Required Registrations:** An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.
 - a. **Data Universal Numbering System:** All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or CoAgs. The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at <http://fedgov.dnb.com/webform/displayHomePage.do>. The DUNS number will be provided at no charge. If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.
 - b. **System for Award Management (SAM):** The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process usually requires not more than five business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.
 - c. **Grants.gov:** The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant website. Registration information is located at the "Get Registered" option at www.grants.gov. All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.
2. **Request Application Package:** Applicants may access the application package at www.grants.gov.
3. **Application Package:** Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

<p>4. Submission Dates and Times: If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by PGO.</p>
<p>a. Letter of Intent (LOI) Deadline: N/A</p>
<p>b. Application Deadline: September 4, 2014. Applications due 11:59 p.m. U.S. Eastern Daylight Time, at www.grants.gov</p>
<p>5. CDC Assurances and Certifications: All applicants are required to sign and submit “Assurances and Certifications” documents located at http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm. Applicants may follow either of the following processes:</p> <ul style="list-style-type: none"> • Complete the applicable assurances and certifications, name the file “Assurances and Certifications” and upload it as a PDF file at www.grants.gov • Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://www.cdc.gov/grantsassurances/Homepage.aspx <p>Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC within one year of the submission date.</p>
<p>6. Content and Form of Application Submission: Applicants are required to include all of the following documents with the application package at www.grants.gov.</p>
<p>7. Letter of Intent (LOI):</p> <p>LOI is not requested or required as part of the application for this FOA.</p>
<p>8. Table of Contents: (No page limit and not included in Project Narrative limit) Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the “Project Narrative” section. Name the file “Table of Contents” and upload it as a PDF file under “Other Attachment Forms” at www.grants.gov.</p>
<p>9. Project Abstract Summary: (Maximum 1 page) A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the “Project Abstract Summary” text box at www.grants.gov.</p>
<p>10. Project Narrative: Maximum of 25 pages, including the Work Plan, single-spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 25 pages will not be considered. For a multi-component FOA, maximum page limit is 30. The maximum page limits for the Prevention and Control, HRD, and Laboratory components between the project narrative and work plan submissions are, 20 pages for Prevention and Control, 2 pages for HRD component, and 8 pages for Laboratory Strengthening.</p>

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section.

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov.

a. Background: Applicants must provide a description of relevant background information that includes the context of the problem. (See CDC Background.)

b. Approach

i. Problem Statement: Applicants must describe the core information relative to the problem for the jurisdictions or populations they serve. The core information must help reviewers understand how the applicant’s response to the FOA will address the public health problem and support public health priorities. (See CDC Project Description.)

ii. Purpose: Applicants must describe in 2–3 sentences specifically how their application will address the problem as described in the CDC Project Description.

iii. Outcomes: Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (i.e., increase, decrease, maintain). (See the program logic model in the Approach section of the CDC Project Description.)

iv. Strategy and Activities: Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Whenever possible, applicants should use evidence-based program strategies as identified by the Community Guide⁵ (or similar reviews) and reference it explicitly as a source. Applicants may propose additional strategies and activities to achieve the outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe the rationale for developing and evaluating new strategies or practice-based innovations. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations: Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

Applicants must file letters of support, as appropriate, name the file “Letters of Support”, and upload it as a PDF file at www.grants.gov.

⁵ <http://www.thecommunityguide.org/index.html>

2. Target Populations: Applicants must describe the specific target population(s) in their jurisdiction. Refer back to the CDC Project Description section – Approach: Target Population.

Inclusion: Applicants must address how they will include specific populations who can benefit from the program, refer back to the CDC Project Description section – Approach: Inclusion.

c. Applicant Evaluation and Performance Measurement Plan: Applicants must provide an overall jurisdiction or community-specific evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement. Applicant must clarify applicability of priority activities in alignment with specific program strategies for scaling up and reaching target populations, settings, and contexts.

The plan must:

- Describe how key program partners will be engaged in the evaluation and performance measurement planning processes.
- Describe the type of evaluations to be conducted (i.e., process and/or outcome).
- Describe key evaluation questions to be answered that are consistent with the activities and outcomes in the work plan.
- Describe other information, as determined by the CDC program (e.g., performance measures to be developed by the applicant) that must be included.
- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Describe how evaluation findings will be used for continuous program and quality improvement.
- Describe how evaluation and performance measurement will contribute to development of that evidence base, where program strategies are being employed that lack a strong evidence base of effectiveness.

Note: Developing an Evaluation and Performance Measurement plan that includes the items listed under the “CDC Project Description” section will meet the expectations listed above. Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach:

Applicant must address the organizational capacity requirements as described in the CDC Project Description. [If CDC requires CVs/Resumes or Organizational Charts then insert: Applicants must name this file “CVs/Resumes” or “Organizational Charts” and upload it at www.grants.gov.]

- Describe how the applicant’s program is organized, the nature and scope of its work and/or the capabilities it possesses.
- Describe experience and success in conducting TB control and prevention activities including development and successful implementation of PE plan and especially aimed at targeted populations.
- Describe how applicant will assess staff competencies and develop a plan to address gaps through organizational and individual training and development opportunities.
- Describe PE focal point person’s readiness and engagement to establish PE in a timely manner, and plan for adaption of successful evidence-based practices for long-term sustainability of the program approaches, if applicable.

11. Work Plan:

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies, and activities, evaluation and performance measurement, including key milestones.

Applicants must name this file “Work Plan” and upload it as a PDF file at www.grants.gov.

12. Budget Narrative:

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative.

The budget must include the following:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Total Direct costs
- Total Indirect costs
- Contractual costs

All contracts require prior approval from CDC. Funds may not be used until the following required information for each contract is submitted to and approved by CDC:

- Name of Contractor: Who is the contractor? Identify the name of the proposed contractor and indicate whether the contract is with an institution or organization.
- Method of Selection: How was the contractor selected? State whether the contract is sole source or competitive bid. If an organization is the sole source for the contract, include an explanation as to why this institution is the only one able to perform contract services.

- **Period of Performance:** How long is the contract period? Specify the beginning and ending dates of the contract.
- **Scope of Work:** What will the contractor do? Describe in outcome terms, the specific services/tasks to be performed by the contractor as related to the accomplishment of program objectives. Deliverables should be clearly defined.
- **Method of Accountability:** How will the contractor be monitored? Describe how the progress and performance of the contractor will be monitored during and on close of the contract period. Identify who will be responsible for supervising the contract.
- **Itemized Budget and Justification:** Provide an itemized budget with appropriate justification. If applicable, include any indirect cost paid under the contract and the indirect cost rate used.

If the above information is unknown for any contractor at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. Copies of the actual contracts should not be sent to CDC, unless specifically requested. In the body of the budget request, a summary should be provided of the proposed contracts and amounts for each.

Required Information for New Consultant Approval: This category is appropriate when hiring an individual who gives professional advice or provides services for a fee and who is not an employee of the grantee organization. All consultants require prior approval from CDC annually. Submit the following required information for new consultant costs:

- **Name of Consultant:** Identify the name of the consultant and describe his or her qualifications.
- **Organizational Affiliation:** Identify the organization affiliation of the consultant, if applicable.
- **Nature of Services to Be Rendered:** Describe in outcome terms the consultation to be provided including the specific tasks to be completed and specific deliverables. A copy of the actual consultant agreement should not be sent to CDC.
- **Relevance of Service to the Project:** Describe how the consultant services relate to the accomplishment of specific program objectives, and unmet needs. A description of the unmet need and how the need was identified should be included in the budget and budget justification section for each new consultant service.
- **Number of Days of Consultation:** Specify the total number of days of consultation.
- **Expected Rate of Compensation:** Specify the rate of compensation for the consultant (e.g., rate per hour, rate per day). Include a budget showing other costs such as travel, per diem, and supplies.
- **Method of Accountability:** Describe how the progress and performance of the consultant will be monitored. Identify who is responsible for supervising the consultant agreement.

If the above information is unknown for any consultant at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. In the body of

the budget request, a summary should be provided of the proposed consultants and amounts for each.

Applicants are encouraged to submit a single budget that reflects true needs for P&C (including HRD) and laboratory. The itemized budget should be based on anticipated funding (similar to submissions in the past), and should also include items to meet needs that cannot be fully addressed with anticipated funds.

TB Prevention and Control (P&C): Applicants should request a true needs budget to include costs associated with outbreak response.

Human Resources Development (HRD): Please include a line-item budget to specify how CoAg funds will be used to achieve your program-specific HRD objectives and activities as stated in this document; seek guidance from your program consultant as needed.

Utilization of funds for training external to the TB program (e.g., National Jewish Health Clinical Course, or an RTMCC course) should be limited to courses that cannot be delivered by the respective TB program as determined by course content and job responsibilities of the participant. Use of HRD funds for this external training need must be specified in the annual Training and Human Resource Development Plan.

For identified high priority needs, such as an outbreak or identified case in a high-risk setting, additional funding and assistance for training and education may be provided as needed via the DTBE Outbreak Response Plan. Organizations with public health training expertise, other state TB control programs with training capacity, or one of the RTMCCs could be utilized via a contract method to deliver training and facilitate HRD activities to address identified outbreak response needs. HRD funds can be used to support travel for the appointed TB training and education focal point to attend the TB ETN/TB PEN conference.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>.

Public Health Laboratory Strengthening: Two budget proposals are requested for the laboratory:

Applicants should submit a true needs budget that includes additional anticipated costs necessary to meet goals associated with strengthening public health laboratory programs.

Note: Budget plans for TB programs shall ensure that at least one key individual attends the annual National TB Conference. Public Health Laboratories are strongly encouraged to ensure at least one individual attends the National Conference on Laboratory Aspects of Tuberculosis.

If applicable and consistent with statutory authority, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see:

<http://phaboard.org>).

Applicant entities include state, local, territorial governments including the District of Columbia, the Commonwealth of Puerto Rico, and the Virgin Islands, or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and tribally designated American Indian or Alaska Native organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file “Budget Narrative” and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect cost rate is a provisional rate, the agreement must have been made less than 12 months earlier. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.

13. Tobacco and Nutrition Policies:

Awardees are encouraged to implement tobacco and nutrition policies. Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies. CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically, The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General

Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: [http://www.gsa.gov/graphics/pbs/Guidelines for Federal Concessions and Vending Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)).

2. Resources that provide guidance for healthy eating and tobacco-free workplaces are: <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
<http://www.thecommunityguide.org/tobacco/index.html>
<http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>.

14. Health Insurance Marketplaces:

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible.

For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review:

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372, which established a system for state and local intergovernmental review of proposed federal assistance applications. Applicants should inform their state single point of contact (SPOC) as early as possible that they are applying prospectively for federal assistance and request instructions on the state's process. The current SPOC list is available at http://www.whitehouse.gov/omb/grants_spoc/.

16. Funding Restrictions:

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research
- Awardees may not use funds for in-patient clinical care; out-patient services are allowed (e.g., tuberculin skin testing, chest radiography, medical evaluation, treatment)
- Awardees may not use funds to supplant state or local health department funds or for inpatient care or construction of facilities
- Awardees may not use funds to purchase drugs for treatment
- Awardees may not use funds for conventional DST reagents/supplies for performing this testing in-house if the current volume is < 50 patient isolates per year for DST
Laboratories with low volume for DST are expected to refer to another laboratory for this service
- Emphasis must be given to directing the majority of funds to core TB control front-line activities, such as case management, completion of treatment, contact investigation,

and outreach activities with strong emphasis on using directly observed therapy (DOT)

- Awardees may also use funds for integration of services when it is intended to specifically reduce TB transmission or improve TB screening, testing or treatment in populations disproportionately affected by other infections or comorbidities including diabetes mellitus, hepatitis B or C virus, STDs, and HIV
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, equipment, and services directly related to core front-line TB control activities
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget
- Supplemental resources from CDC should be used in accordance with CDC recommendations (i.e., both established guidelines and other recommendations tailored to a specific setting that follow investigation assistance by CDC)
- Reimbursement of pre-award costs is not allowed
- Other than for normal and recognized executive-legislative relationships, no funds may be used for the following:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement \(AR\) 12](#) for detailed guidance on this prohibition and [additional guidance on lobbying for CDC awardees](#).
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Public Health Laboratory Strengthening

Laboratories performing first-line DST for < 50 patient isolates/ year should refer isolates to a higher volume reference laboratory for testing.

http://www.aphl.org/aphlprograms/infectious/tuberculosis/Documents/ID_2007Dec_TB-DST-Report.pdf

As such, laboratories reporting, as part of this application, DST for < 50 patient isolates/ year may not request funding support for reagents and supplies associated with conventional DST. Requests for these items will be denied. Laboratories within this category may request the use of funds for shipping supplies and costs for access to referral services.

17. Other Submission Requirements:

- a. **Electronic Submission:** Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov.

Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO Technical Information Management Section (TIMS) staff at 770-488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

- b. Tracking Number:** Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.
- c. Validation Process:** Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as 2 business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.
If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Application User Guide, Version 3.0, page 57.
- d. Technical Difficulties:** If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Applications submitted by email or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
- e. Paper Submission:** If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or email them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may email or call CDC GMO/GMS, before the deadline, and request

permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the case number assigned to the inquiry;
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Application Review Information

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review:

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by NCHHSTP/DTBE and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review:

A review panel will evaluate complete, eligible applications in accordance with the "Criteria" section of the FOA.

I. Approach: (30 points)

- **Problem statement: (3 points)**

Applicant adequately described the core information relative to the public health problem in order to understand how the application response to the FOA will address the problem for the jurisdiction or population served

- **Purpose: (2 points)**

Applicant adequately described how the application will address the public health problem identified in the problem statement

- **Collaboration: (3 points)**

Applicant adequately described how they will collaborate with CDC funded programs in their jurisdiction as well as external organizations such as Medicaid programs, health plans, primary care settings, safety-net providers, not-for-profit clinics, correctional settings, homeless shelters, community-based organizations, tribal communities, academic experts and others in their jurisdiction.

- **Target populations: (4 points)**

Applicant identified the target populations in their jurisdiction and the application

addressed how they will include specific populations who can benefit from the program. These include all persons with TB disease; foreign-born persons residing in, or traveling to, the United States; racial and ethnic minority populations; persons living with HIV and/or diabetes mellitus; and persons working or residing in congregate settings (e.g., correctional facilities, homeless shelters) to address social determinates of health.

- **Outcome: (8 points)**

Application adequately described the project period outcomes the applicant intends to achieve in order to reduce TB morbidity and mortality in their jurisdiction

- P&C - Increased proportion of Completion of Treatment; Increased drug susceptibility result reporting (DST); Improved program ability to effectively and efficiently adopt available state-of-the art technologies (diagnostics & treatment), and improved use of local data for greater effectiveness and transparency.
- HRD - Improved TB program's ability to be prepared and informed to translate knowledge and skills into practice.
- Laboratory Strengthening - Improvements in turn-around-times (TATs), advancement in efficiencies based on implementation of evidence-based policies and procedures, and enrichment of collaborations. Prepared and informed TB public health staff and other partners regarding recommended practices for TB diagnosis and treatment.

- **Strategies and Activities: (10 points)** Applicant provided clear and concise description of the strategies and activities that will be used to achieve project period outcomes

- P&C – The application described which of the three tiers applied to the jurisdiction based on the definition in the FOA, and the appropriate priority level program activities identified in the FOA that will be employed to achieve project period outcomes
- HRD – An individual was identified to serve as the focal point for training and education, and their duties and responsibilities are clearly described. The application described how the training and human resources development plan will accomplish the activities listed in the FOA (or should we expand by including how the plan will improve existing training and systems; identify ongoing training and development needs; improve patient education and internal communication capacity; coordinate training with other disease control interventions (i.e., HIV/AIDS, viral hepatitis, and STD); and target other providers or organization serving high-risk populations)
- Laboratory – The application adequately described how laboratory would ensure improvements in TATs, advancement in efficiencies based on implementation of evidence-based policies and procedures, and enrichment of collaborations. The laboratory activities described in the application include all those listed in the

FOA.

II. Evaluation and Performance Management: (20 points)

- How complete is the application in describing the Performance Measurement Strategies as described in the FOA? (See CDC Project Description.) **(10 points)**
- How complete is the application in describing the Performance Measurement Plan to achieve the outcomes as described in the FOA? (See CDC Project Description.) **(10 points)**

III. Applicant's Organizational Capacity to Implement the Approach: (50 points)
TB Prevention and Control (P&C) (35 points)

The Work Plan must address the following at minimum:

- Specify priority level to be used for project period and its alignment with the program strategies.
- Describe activities within selected priority level for the project period and related objectives, milestones, and intended outcomes with timelines, and they must be in alignment with chosen priority and program strategies.
- Discuss how information gathering, monitoring, analysis, and dissemination will be used to address program priority activities
- Discuss how to support a health equity approach in program services and activities including whether a PCSI model is utilized
- Describe plan for data gathering, analyzing, reporting of health equity that have greatest impact on reducing health disparities
- Describe P&C efforts among target populations and settings documented to have a high risk for TB (e.g., foreign-born persons, homeless shelters, correctional facilities, other congregate settings)
- Include monitoring and evaluation plan for milestones accomplishing during the project period
- Describe administration and assessment process to ensure successful implementation and quality assurance
- Describe staff and administrative roles and functions to support implementation of the FOA

Human Resource Development (HRD) (5 points)

The Work Plan must address the following:

- Identify a program focal point for Training and Education; ensure this person is a member of TB ETN.
 - Name
 - Job title
 - Mailing address
 - Telephone
 - FAX number
 - Email address
 - Date this person became TB ETN member

- Describe the applicant's 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 development 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, viral hepatitis, and STD.
 - Target other health care providers or organizations serving high-risk populations.

For your assistance, an example of some activities and outcomes are provided below.

Outcome 1: By February 28, 2015, a TB training and education focal point will be designated.

- Identify TB program staff person to serve in this capacity.
- Revised job description/work plan will include this duty as an essential element.
- Designated TB training focal point will join TB ETN (if not already a member).
- Designated TB training focal point will attend Focal Point meeting and TB ETN annual conference in August.

Outcome 2: By May 1, 2015, the two medical consultants for the TB program will be enrolled or have attended a TB update course at the RTMCC or another TB clinical course such as those offered by the National Jewish Hospital.

- Identification of clinical training options by the TB training focal point.
- Select appropriate training course(s) for TB medical consultants.

Outcome 3: By September 1, 2015, a series of in-service training sessions will be developed and delivered for state TB program staff.

- Contact regional managers to coordinate development of TB training sessions based on identified needs
- Contact designated RTMCC for assistance in developing training session objectives and materials
- Deliver training session(s)
 - Conduct or provide tuberculin skin test training course
 - Conduct or provide TB Nurse case management course

Outcome 4: By September 1, 2015, a series of in-service training sessions will be developed and delivered for state STD and HIV program staff in conjunction with the respective program training coordinators on basic facts on TB, including transmission and pathogenesis, identification of high risk populations, testing, and follow-up.

- Contact STD and HIV program training coordinators to coordinate development of TB training sessions based on identified needs
- Contact designated RTMCC for assistance in developing training session objectives

and materials

- Deliver training session(s)
- Conduct or provide tuberculin skin test training course

Public Health Laboratory Strengthening: (10 points)

The Work Plan must address the following:

- Laboratory organizational chart with designated laboratory contact
- Brief description of laboratory methods, workflow, and testing algorithms
- Annual workload and TAT data for the most recent calendar year and year-to-date
- Strategies and activities for meeting defined outcomes for each Laboratory Component appropriate to the laboratory level of service and workload
 - **Element 1:** Ensuring availability of high-quality and prompt core laboratory services that meet CDC and Healthy People 2020 recommended TATs.
 - **Element 2:** Promoting continual advancement of laboratory efficiency and quality assurance through use of local data.
 - **Element 3:** Collaborating with partners to ensure optimal use of laboratory services.

Not more than 30 days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or submission requirements.

2. Announcement and Anticipated Award Dates:

Awards will be announced via electronic copy of the Notice of Award (NoA) from CDC PGO on December 1, 2014.

F. Award Administration Information

1. Award Notices:

Awardees will receive an electronic copy of the Notice of Award (NoA) from CDC PGO. The NoA shall be the only binding, authorizing document between the awardee and CDC. The NoA will be signed by an authorized GMO and emailed to the awardee program director.

Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by email with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements:

Awardees must comply with the administrative requirements outlined in 45 CFR. Part 74 or Part 92, as appropriate. Brief descriptions of relevant provisions are available at http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

The following Administrative Requirements (ARs) apply to this project:

- ✓ AR-7: Executive Order 12372
- ✓ AR-9: Paperwork Reduction Act
<http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html>
- ✓ AR-10: Smoke-Free Workplace
- ✓ AR-11: Healthy People 2010
- ✓ AR-12: Lobbying Restrictions
- ✓ AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- ✓ AR-14: Accounting System Requirements
- ✓ AR-24: Health Insurance Portability and Accountability Act
- ✓ AR-25: Release and Sharing of Data
- ✓ AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging While Driving," October 1, 2009
- ✓ AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- ✓ AR-33: Plain Writing Act of 2010
- ✓ AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)
- ✓ AR-6: Patient Care ARs applicable to awards related to conferences
- ✓ AR-20: Conference Support
- ✓ AR-27: Conference Disclaimer and Use of Logos

For more information on the CFR, visit the National Archives and Records Administration at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

3. Reporting

a. CDC Reporting Requirements:

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it

- ✓ Helps target support to awardees, particularly for cooperative agreements;
- ✓ Provides CDC with periodic data to monitor awardee progress towards meeting the FOA outcomes and overall performance;
- ✓ Allows CDC to track performance measures and evaluation findings to validate continuous program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- ✓ Enables CDC to assess the overall effectiveness and influence of the FOA.

As described in the following text, awardees must submit an annual performance report,

ongoing performance measures data, administrative reports, and a final performance and financial report. A detailed explanation of any additional reporting requirements will be provided in the Notice of Award to successful applicants.

b. Specific reporting requirements:

i Awardee Evaluation and Performance Measurement Plan: Awardees must provide a more detailed evaluation and performance measurement plan within the first six months of the project. This more detailed plan must be developed by awardees as part of first-year project activities, with support from CDC. This more detailed plan must build on the elements stated in the initial plan, and must be no more than 25 pages. At a minimum, and in addition to the elements of the initial plan, this plan must:

- Indicate the frequency that evaluation and performance data are to be collected.
- Describe how data will be reported.
- Describe how evaluation findings will be used to ensure continuous quality and program improvement.
- Describe how evaluation and performance measurement will yield findings that will demonstrate the value of the FOA (e.g., effect on improving public health outcomes, effectiveness of FOA as it pertains to performance measurement, cost-effectiveness, or cost-benefit).
- Describe dissemination channels and audiences (including public dissemination).
- Describe other information requested and as determined by the CDC program.

When developing evaluation and performance measurement plans, applicants are encouraged to use the Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide, available at: <http://www.cdc.gov/eval/guide/index.htm>

ii Annual Performance Report: This report must not exceed 45 pages excluding administrative reporting; attachments are not allowed, but Web links are allowed. The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period. In addition, the awardee must submit an annual Federal Financial Report within 90 days after the end of the calendar quarter in which the budget year ends.

The Annual Performance Report (APR) replaces the Annual Progress Report and the Interim Progress Report used in previous project periods; they have been combined into one report. Awardees must ensure that the information provided in the new APR serves both purposes previously provided by the annual and interim progress reports. In addition to being a report on all performance measures, including progress towards meeting outcomes, the APR also serve as the awardee's application for continued funding (formerly referred to as the Interim Progress Report). For the purposes of performance reporting, the APR should include an overview of progress and associated data for the previous calendar year (i.e., January–December) and year to date (i.e., January–June).

The APR should cover each budget period (BP) throughout the 5-year project period as follows:

- In BP 2015, the APR will be due August 31 for the activities performed January 1, 2015 through June 30, 2015.
- For BPs 2016–2019, APRs will be due on August 31 of each year and should include a description of the TB program and laboratory activities/strategies implemented and progress made in achieving outcomes during the prior calendar year (January 1–December 31) and an update of activities/strategies and outcomes achieved during the first 6 months (January 1–June 30) of the current year. Data and associated information should be stratified by budget year (i.e., do not report as a single 18 month period).
- For each APR, the report should include a description of proposed activities and outcomes for the next budget year to serve as part of the continuation application.

Within the 45-page limit of the APR, awardees should use a maximum of 30 pages for P&C; 5 pages for HRD; and 10 pages for Laboratory Strengthening to cover performance reporting and continuation funding application.

The guide below should be used in reporting on the specific performance and outcomes for the P&C, HRD, and Laboratory Components:

- ✓ **Performance Measures** (including outcomes)—Awardees must report on performance strategies and activities for each budget period and update measures, if needed.
- ✓ **Evaluation Results**—Awardees must report evaluation results for the work completed to date (including any data about the effects of the program).
- ✓ **Work Plan**—Awardees must update work plan each budget period.
- ✓ **Successes**
 - Awardees must report progress on completing activities outlined in the work plan.
 - Awardees must describe any additional successes (e.g., identified through evaluation results or lessons learned) achieved in the past year.
- ✓ **Challenges**
 - Awardees must describe any challenges that might affect their ability to achieve annual and project-period outcomes, conduct performance measures, or complete the activities in the work plan.
 - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- ✓ **CDC Program Support to Awardees**
 - Awardees must describe how CDC could help them overcome challenges to achieving annual and project-period outcomes and performance measures, and completing activities outlined in the work plan.
- ✓ **Administrative Reporting** (No page limit)
 - SF-424A Budget Information-Non-Construction Programs.
 - Budget Narrative—must use the format outlined in “Content and Form of Application Submission, Budget Narrative” section.
 - Indirect Cost-Rate Agreement.

Performance and outcome reporting requirements specific to each component are as follows:

Prevention and Control (P&C):

- a. One-page summary report on National TB Program Objectives using NTIP system including a description of which objectives were met and what the impediments were to meeting the objectives.
- b. Report on the priority level activities highlighting successful outcomes, including developing benchmarks for specific activities.
- c. Report of an integrated approach, such as PCSI, which was undertaken to foster collaboration and coordination of proposed activities in the work plan.
- d. Report describing barriers and challenges to program implementation of the proposed priority level strategies/activities that were encountered; how was the planned program modified to accommodate them?
- e. PE annual report must have the followings four sections (i–iv) and address the relevant components:
 - i. Introduction: Description of the Evaluation Objectives
 1. Describe the purpose of your evaluation
 2. Provide rationale for selecting evaluation focus area
 3. State how NTIP and/or other data sources were used to select evaluation focus area
 4. Define the evaluation objectives and key evaluation questions to be answered that are consistent with the activities and outcomes in the work plan
 5. Identify expected outcomes (short, medium, long)
 - ii. Description of Data Collection and Analyses for Each Evaluation Objective.
 1. Describe the type of evaluation (process and outcome)
 2. Describe how and when the evaluation was conducted (list activities and timeline)
 3. Describe data sources
 4. Describe methodology for data collection and analysis
 - iii. Conclusion and Discussion of Results.
 1. Provide results of the proposed evaluation objectives/key questions. If not achieved, why not? Discuss barriers to and facilitators of achieving the objective(s).
 2. Provide an interpretation of results for each evaluation objective/key questions.
 3. Provide a statement of findings with respect to evaluation in attaining the National TB Program Objectives (how evaluation findings can be linked with the objectives).
 4. Discuss limitations that may have affected the evaluation's findings.
 - iv. Recommendations to Program Administrators for Future Program Focus and Evaluation Efforts.
 1. Describe the emerging, promising, and best and/or evidence-based practices.
 2. List the lessons learned and program recommendations based on the evaluation findings.
 3. Identify the next focus area for evaluation.
 4. Identify plans to share lessons learned (i.e. webinars, conferences, publications).

- f. Cohort Review Reports: Grantees should report the progress on conducting cohort reviews, including the number of cases discussed, key issues identified during the reviews and recommendations provided.

Format for Cohort Review Reporting:	
Element	Progress
Date(s) of Cohort Review(s)	
Number of cases discussed (per review/total)	
Summary of review process	
Key Issues Identified and resolved	
Recommendations	
New tools or trainings	

The Designated Evaluation Focal Point:

- Name:
 Job title:
 Mailing address:
 Telephone:
 FAX number:
 Email:

Human Resources Development:

Grantees should report on progress of HRD activities and achievements for the previous year. The report should include, but not limited to, description of utilization of funds; training courses conducted or attended; educational resources purchased or leased; attendance at TB ETN conference and focal point meeting; and salary for training and education personnel.

The Annual HRD Progress Report should also include a description of how identified needs were addressed, as well as barriers and opportunities identified in the area of TB HRD.

Please list objectives and activities to

1. Establish and improve existing in-service TB training and human resource development.
2. Establish evaluation strategies to improve existing systems and to identify ongoing training and HRD needs.
3. Establish and improve patient education and communications capacity within the program.
4. Coordinate training related to TB control with training for other disease control interventions, such as HIV/AIDS, viral hepatitis, and STD.
5. Target other health care providers or organizations serving high-risk populations.

Public Health Laboratory Strengthening:

- a. Update work plan (i.e., organizational charts, laboratory contact, methods, and TAT and

workload data).

- b. Report on success and challenges for strategies and activities in meeting proposed outcomes for each laboratory element based on level of service and workload.
- **Element 1:** Ensuring availability of high-quality and prompt core laboratory services that meet CDC and Healthy People 2020 recommended TATs.
 - **Element 2:** Promoting continual advancement of laboratory efficiency and quality assurance through use of local data.
 - **Element 3:** Collaborating with partners to ensure optimal use of laboratory services.

Propose new activities for next budget year to continue progress toward meeting stated outcomes. The following instructions should be used as guide in providing the information that will serve as the application for the next budget year funding.

General Application Packet Tips:

- Properly label each item of the application packet
- Each section should use 1.5 spacing with one-inch margins
- Number all narrative pages only
- Use a 12 point font
- Where the instructions on the forms conflict with these instructions, follow these instructions:
 1. CDC requires the use of PDF format for ALL attachments.
 2. Use of file formats other than PDF may result in the file being unreadable by CDC staff.
 3. Directions for creating PDF files can be found on www.grants.gov.

Checklist of required contents of application packet:

- Application for Federal Domestic Assistance-Short Organizational Form
- SF-424A Budget Information-Non-Construction Programs
- Budget Justification
- Indirect Cost Rate Agreement
- Project Narrative outlining the goals and objectives for the application year

Instructions for accessing and completing required contents of the application package:

- Go to: www.grants.gov
- Select: "Apply for Grants"
- Select: "Step 1: Download a Grant Application"
- Insert the Funding Announcement Number only, formatted as: PS-XX-XXXXCONT(FY)
- Download application package and complete all sections

Content of application packet:

1. Application for Federal Domestic Assistance-Short Organizational Form:
 - A. Complete all sections.
 - I. In addition to inserting the legal name of your organization in Block #5a, insert the CDC Award Number provided in the CDC Notice of Award. Failure to provide your

award number could cause delay in processing your application.

II. Please insert your organization's Business Official information in Block #8.

SPECIAL NOTE: Items 2, 3, and 4 below should be attached to the application through the "Mandatory Documents" section of the "Grant Application" page. Select "Other Attachments Form" and attach as a PDF file.

2. SF424A Budget Information and Justification:

- A. Download the form from www.grants.gov.
- B. Complete all applicable sections.
- C. Estimated Un-obligated:
 - I. Provide an estimate of anticipated un-obligated funds at the end of the current budget period.
 - II. If use of estimated un-obligated funds is requested in addition to funding for the next year, complete all columns in Section A and submit an interim electronic Federal Financial Report, SF-425/SF-425A available at <http://grants.nih.gov/grants/forms.htm#closeout>.
- D. The estimated un-obligated balance should be realistic in order to be consistent with the annual Federal Financial Report (FFR) to be submitted following the end of the budget period.
- E. Based on the current rate of obligation, if it appears there will be un-obligated funds at the end of the current budget period, provide detailed actions that will be taken to obligate this amount.
- F. If it appears there will be insufficient funds, (1) provide detailed justification of the shortfall; and (2) list the actions taken to bring the obligations in line with the authorized funding level; and (3) provide a "true needs budget" to include activities planned in the event there are supplemental funds (e.g., outbreak investigations, surveillance, contracted services lost due to budget cuts, other special needs).
- G. The proposed budget should be based on the federal funding level stated in the letter from CDC.
- H. In a separate narrative, provide a detailed, line-item budget justification of the funding amount requested to support the activities to be carried out with those funds. Attach in the "Mandatory Documents" box under "Budget Narrative Attachment Form". Document needs to be in the PDF format.
- I. The budget justification must be prepared in the general form, format, and to the level of detail as described in the CDC Budget Guidance. The sample budget guidance is provided on CDC's internet at: <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>.
- J. For any new proposed subcontracts provide the information specified in the Budget Guidance.
- K. When non-federal matching is required, provide a line-item list of non-Federal contributions including source, amount, and/or value of third party contributions proposed to meet a matching requirement.

3. Indirect Cost Rate Agreement: (This is not applicable to grantees subject to the Office of Management and Budget [OMB] Guidance A-21 – Educational Institutions. The rates stay the same as the first year award.)

- A. If indirect costs are requested, include a copy of the current negotiated Federal Indirect Cost Rate Agreement or a cost allocation plan approval letter for those grantees under such a plan.
- B. Clearly describe the method used to calculate indirect costs. Ensure the method is consistent with the Indirect Cost Rate Agreement.
- C. To be entitled to use indirect cost rates, a rate agreement must be in effect at the start of the budget period.
- D. If an Indirect Cost Rate Agreement is not in effect, indirect costs may be charged as direct if (1) this practice is consistent with the grantee's/applicant's approved accounting practices; and (2) if the costs are adequately supported and justified. Please see the Budget Guidelines for additional information.
<http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>
- E. If applicable, attach in the "Mandatory Documents" box under "Other Attachments Form," and name the document, "Indirect Cost Rate."

4. New Budget Period Proposed Activities and Outcomes(Year XXXX):

- A. List proposed activities for the upcoming budget period. These activities must support the intent of the original Funding Opportunity Announcement (FOA).
- B. Each activity must contain a performance or outcome measure that assesses the effectiveness of the project.
- C. For each outcome:
 - I. List activities that will be implemented;
 - II. Provide a timeline for accomplishment;
 - III. Identify and justify any redirection of activities; and
 - IV. Explain the methods you will use to implement the new, redirected activities.
- D. In addition to this information, include comments pertaining to budgetary issues that might hamper the success or completion of the project as originally proposed and approved. Please utilize the work plan format in the original work plan, if applicable.

Other Relevant Information:

As stipulated in the original FOA for the current project period the Aggregate Report for Program Evaluation (ARPE) is due on August 15. The Final ARPE report is due for the current year minus two (for example, in 2015, the Final report is due for year 2013). The Preliminary ARPE report is due for the current year minus one (for example, in 2015, the Preliminary report is due for year 2014). In year 2015, the Final 2013 and Preliminary 2014 will be due.

Note: The National TB Indicators Project (NTIP) has performance outcome reports for each project area. You may use these reports in your analysis, and for comparison with state and local data. Access can be found at ntip@cdc.gov, or contacting the helpdesk at 404-639-8444;

Hours: 8 a.m.–5 p.m. (EST), Monday–Friday.

For year 2 and beyond, awardees may request that estimated unobligated funds be carried over into the next budget period. The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.
- Include third party contributions and budget gaps.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

iii. Performance Measure Reporting: CDC programs must require awardees to submit performance measures annually as a minimum, and may require reporting more frequently. Performance measure reporting must be limited to data collection. When funding is from CDC programs must specify required reporting frequency, data fields, and format.

Awardees will meet this annual requirement to report on performance measures with the submission of an Annual Performance Report. However, CDC may request an additional report, the Performance Measure Report, in certain instances such as a jurisdiction's response to a large TB outbreak.

Performance Measure Reports should at minimum include:

- Report on the activities completed
- Outcomes achieved
- Challenges experienced
- Program improvements as applicable
- Additional support (if any) requested from CDC

Awardees submitting Performance Measure Reports for response to large TB outbreaks should provide a report 90 days following the response and quarterly thereafter for the first year of outbreak response, and at least semiannually thereafter until the outbreak subsides.

iv. Federal Financial Reporting (FFR): The annual FFR form (SF-425) is required and must be submitted through eRA Commons³³ within 90 days after each budget period ends. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final report must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. The final FFR expenditure data and the Payment Management System's cash transaction data must correspond; no discrepancies between the data sets are permitted. Failure to submit the required information by the due date may adversely affect future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation and

include the date by which the information will be provided.

- v . Final Performance and Financial Report:** At the end of the project period, awardees must submit a final report including a final financial and performance report. This report is due 90 days after the project period ends. (CDC must include a page limit for the report with a maximum of 40 pages).

At a minimum, this report must include:

- Performance Measures (including outcomes)—Awardees must report final performance data for all performance measures for the project period.
- Evaluation Results—Awardees must report final evaluation results for the project period.
- Impact/ Results—Awardees must describe the effects or results of the work completed over the project period, including success stories.
- Additional forms as described in the Notice of Award, including Equipment Inventory Report and Final Invention Statement.

Awardees must email the report to the CDC Project Officer (PO) and the GMS listed in the “Agency Contacts” section of the FOA.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA):

The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible website, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than \$25,000. For the full text of these requirements, see:

<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=BILLS>.

G. Agency Contacts

For **programmatic technical assistance**, contact:

Glenroy Christie, MPH
Deputy Branch Chief, Field Services and Evaluation Branch
Division of Tuberculosis Elimination
Centers for Disease Control and Prevention
1600 Clifton Road, NE. MS: E10
Atlanta, GA 30333
Telephone: 404-639-8133
e-mail: gchristie@cdc.gov

For **laboratory technical assistance**, contact:

Angela Starks, Ph.D.
Chief, Laboratory Branch
Division of TB Elimination
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333
Telephone: 404-639-3205
e-mail: astarks@cdc.gov

For **financial, awards management, or budget assistance**, contact:

Edna Green, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-15
Atlanta, GA 30341
Telephone: 770-488-2858
e-mail: egreen@cdc.gov

For **submission difficulties related to www.grants.gov**, call the Contact Center at 1-800-518-4726; Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:

*Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
e-mail: pgotim@cdc.gov*

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

Following is a list of acceptable attachments that applicants can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative

- CDC Assurances and Certifications
- Work Plan
- Table of Contents for Entire Submission
- Resumes/CVs
- Letters of Support
- Organizational Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate, if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

I. Glossary

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Calendar Day: Successive days, not working days. This includes days the laboratory is not open for business (weekends, holidays).

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A catalog published twice a year that describes domestic assistance programs administered by the federal government. This catalog lists projects, services, and activities that provide assistance or benefits to the American public. This catalog is available at <https://www.cfda.gov/index?s=agency&mode=form&id=0bebbc3b3261e255dc82002b83094717&tab=programs&tabmode=list&subtab=list&subtabmode=list>.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the duration of the award).

Clinical Specimen: Sample derived directly from a patient (e.g., sputum, cerebral spinal fluid) that is submitted to the laboratory for testing.

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument that establishes a binding, legal procurement relationship between CDC and a recipient, and obligates the recipient to furnish a product.

Cooperative Agreement (CoAg): A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award.

Cost Sharing or Matching: Refers to program costs not borne by the federal government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: An assistance support mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. Direct assistance generally involves the assignment of Federal personnel or the provision of equipment or supplies, such as vaccines. <http://intranet.cdc.gov/ostlts/directassistance/index.html>.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the internet, obtaining a DUNS number may take 1 to 2 days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at <http://fedgov.dnb.com/webform/displayHomePage.do>.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year (FY) starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A web portal for electronic data collection (forms and reports) for federal grant-making

agencies at www.grants.gov.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Individual patient: One unique patient.

Initial diagnostic specimen: First clinical specimen received in your laboratory from an individual patient with a positive result (identification or drug susceptibility test). This does not include follow-up specimens. This should include clinical specimens referred to another laboratory for testing.

Initial M. tuberculosis complex isolate: First M. tuberculosis complex (MTBC) isolate recovered from an individual patient. For example, if two sputum specimens were submitted on Patient "A," one on September 10 and one on September 12, and the first M. tuberculosis isolate identified was from the specimen submitted on September 12, then this would be the "initial isolate," even if M. tuberculosis grows from the September 10 specimen.

Intergovernmental review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following Web address to get the current SPOC list: http://www.whitehouse.gov/omb/grants_s poc/.

Isolate: Organism obtained by processing and culturing a clinical specimen.

Jurisdiction: State, city, or county covered by the Cooperative Agreement.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other nongovernment sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Matching: See “Cost Sharing or Matching.”

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

NAAT: Nucleic acid amplification test for the detection of M. tuberculosis complex performed directly on a clinical specimen.

New Funding Opportunity Announcement (FOA): Any FOA that is not a continuation or supplemental award.

Nongovernment Organization (NGO): Any nonprofit, voluntary citizens' group that is organized on a local, national, or international level.

Notice of Award (NoA): The only binding, authorizing document between the recipient and CDC that confirms issue of award funding. The NoA will be signed by an authorized GMO and provided to the recipient fiscal officer identified in the application.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A “program” may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The observable benefits or changes for populations or public health capabilities that will result from a particular program strategy.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Public health interventions or public health capabilities.

Program Official: Person responsible for developing the FOA; can be a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA’s funding period.

Public Health Accreditation Board (PHAB): National, nonprofit organization that improves tribal,

state, local, territorial, and U.S. public health departments and strengthens their quality and performance through accreditation.

Rapid Detection Test: Test for the detection of the presence of *M. tuberculosis* complex (MTBC) performed directly on a clinical specimen (e.g., NAAT, direct high-performance liquid chromatography [HPLC]). This does not include rapid species identification tests performed on isolates such as ACCUProbe.

Reference Isolate: Organism obtained by processing and culturing a clinical specimen in another laboratory that is referred to your laboratory for testing. This includes isolates referred on solid and in liquid media.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations. *Black's Law Dictionary 2 Kent, Comma 450.*

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of annual strategies and activities, personnel and/or partners who will complete them, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

PS15-1501: Tuberculosis Elimination and Laboratory Cooperative Agreement Funding Opportunity Announcement Questions & Answers

1. What is page limit?

Page limit refers to the number of pages allowed for certain documents required by the FOA. The total page limit for the Prevention and Control (P&C), Human Resource Development (HRD) and Laboratory narrative and work plan is 30 pages. By component, the page limit for P&C is 20 pages (including 5 pages for the Program Evaluation (PE) plan), the page limit for HRD is 2 pages, and the page limit for Laboratory is 8 pages. The budget has no page limit.

2. What is format or desired recommended template for response?

Any format that provides clear and relevant information in response to the required submissions in the FOA is acceptable.

3. Should objectives focus on NTIP indicators?

The use of the term “objectives” is de-emphasized in this FOA. Rather, Strategies, Activities, as well as short-, intermediate- and long-term outcomes are used. When programs report (Annual Performance Reports), they are to address in one page which of the National TB Program Objectives were met, and what the impediments were to meeting the objectives. National TB Program Objectives are also among the data sources to be used when programs select evaluation criteria.

4. Should the P & C budget be a single document reflecting true needs or should there be two documents with one written for the funding level and the second a true needs budget?

Applicants are encouraged to submit a single budget that reflects true needs for P&C (including HRD) and laboratory. The itemized budget should be based on anticipated funding (similar to submissions in the past), and should also include items to meet needs that cannot be fully addressed with anticipated funds.

Although submitting a single budget, there should be a clear distinction between funding for items based on anticipated funds; and funding of items for needs beyond what anticipated funds are expected to address. Examples of such needs are activities for program improvements, goals associated with all aspects of strengthening public health laboratory program, and potential emergencies (e.g., large outbreaks, cluster investigations; or influx of unaccompanied children, refugees, or migrants with TB infection and disease).

5. **What is the difference between the Project Narrative and the work plan? Are both required? On page 34, it states a work plan file should be uploaded in grants.gov. On page 31, the work plan is referenced as a part of the Project Narrative?**

The project narrative addresses the information presented in the CDC Project Description of the FOA (i.e. background, approach, applicant evaluation and performance measurement plan and organizational capacity of applicants to implement the approach. The work plan is high-level and covers the duration of the project, with more detail for the first year of the project period. The components in the work plan should clearly address the crosswalk to the outcomes, strategies and activities, and performance measures presented in the logic model and narrative sections. Both are required, and the work plan is included in the page limit for the project narrative. The project narrative and work plan can be submitted as one document, as long as both are within the total page limit (30) for the project narrative specified in the FOA and the work plan is clearly identified as such. If submitted as a single upload, label the upload, "Project Narrative".

6. **Although cost sharing and matching is strongly encouraged but not required (page 3), are jurisdictions asked to provide information related to what and how other resources are leveraged? How is this to be reported?**

Cost sharing is not required by the FOA; however, if cost sharing is reported, the information must be reported on Standard Form 424A and mentioned in the budget narrative. The Standard Form 424A provides a column for this information.

7. **Where is the language regarding the need to include budget for travel to the annual National TB Conference? As the FOA is currently written, TB PEN attendance is only "encouraged" (page 13) but language should be stronger to ensure that this is included in the response?**

The current FOA is being amended to address this concern.

8. **Emphasis is placed on collaboration with other CDC-funded programs and organizations external to CDC. Specifically related to PCSI, there is reference to funds being utilized to hire additional staff focused on this. Was this same language included in the HIV, STD and Hepatitis cooperative agreements? Could those agreements be encouraged to fund the majority of personnel given the larger total award amounts?**

There is similar language regarding PCSI in other FOAs from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). Programs must use their awarded funds to address the disease in the FOA; however, they may combine funds to cover budget items such as personnel performing activities related across NCHHSTP cooperative agreements.

9. **In the HRD section (page 36) and instructions on the required line-item budget, there is reference to utilizing a contract method with other state TB control programs, or the RTMCCs, to provide training in high priority needs, such as an outbreak or case in a high-risk setting. Is this suggesting that the proposal budget include payment for services of the RTMCCs? Are these services/trainings not provided as part of the RTMCC's cooperative agreements?**

No, we are not suggesting the use of CoAg funds for RTMCC services. This reference in the FOA was to clarify that for any identified high priority need, such as an outbreak or identified case in a high-risk setting, additional funding and assistance for training and education may be provided by CDC via the DTBE Outbreak Response Plan. The amended FOA will clarify.

10. **Last year we received email communication from PGO with our award numbers as well as our state award number that needed to be entered in the application package. Has or will we receive a similar communication from PGO?**

This FOA is for a new competitive announcement and award numbers will be established upon submission of the applications. New award numbers will be provided to the selected applicants during budget discussions.

11. **Must all seven "strategies" be addressed for each population or NTIP objective?**

The seven strategies, or portions thereof, should be addressed based on a program's assigned Tier. The NTIP indicators should still be used in developing program outcomes over the five-year project period.

12. **Under each strategy, there is a statement re ..."the following should be conducted", followed by a list of bulleted statements. What terminology is appropriate for these bulleted items?**

The bulleted items under each strategy are the activities to conduct in support of the strategy. The work plan should describe how these activities would be conducted.

13. **Within the total page limit there are also references to maximum number of pages per certain sections. How important are those limitations as long as the total page number does not exceed the maximum?**

See answer to question #1. Documents must stay within applicable page limits.

14. **The laboratory instructions are very specific about two distinct budgets, the program section is not so clear. Do you want two budgets for each section of the application?**

See earlier response to question #4.

15. Are CVs/Resumes or Organizational Charts required as part of the application?

Yes, since this is a new FOA and the first year of the new project period, CVs/resumes are required for key personnel, e.g., Principal Investigator, TB Program Managers, Microbiology Supervisor, or Mycobacteriology Supervisor. This requirement will be clarified in the amended FOA.

16. Given that the work plan is included in the page limit for the project narrative, do programs have to upload two separate submissions labelled "Project Narrative" and "work plan" or can they be submitted as one upload?

The content of the project narrative and work plan submission combined must meet the 30-page limit stated in the FOA; however, they can be uploaded as a single submission labelled "project narrative". The work plan must be clearly identified as such.

17. Does the one-page Project Abstract Summary count in the 30-page limit for the Project Narrative?

No, the Project Abstract Narrative (maximum 1-page) is not included in the 30-page limit for the Project Narrative.

18. The Narrative/Work plan format is different from the Annual Performance Report (APR) format. The narrative is single spaced and the APR is 1.5 spaces. Please confirm or clarify.

The project narrative and work plan must be single-spaced, Calibri 12 point font in the application submission in accordance with the approved template for CDC non-research FOAs. The 1.5 line spacing for the APR is consistent with the format used with Interim Progress Reports (IPR) in the past that also served as application for continuing funding, and CDC would like to maintain that format.

19. Project Narrative format--on pg. 31 #10 it states "The Project Narrative must include all of the bolded headings shown in this section." Can you please confirm the bolded headings that should be included?

All the bolded headings on page 32-33 should be included.

20. Do letters of support, CVs/Resumes or organizational charts submissions count against the 30-page limit for the project narrative submission?

No, these separately labelled uploads do not count against the page limit for the project narrative.

21. **Based on the guidance in the “application and Submission Information” section on what should be in the Evaluation and Performance Measurement plan and the guidance in the “Evaluation and Performance Measurements” section under the CDC Project Description, it seems like two different evaluation plans are required. Is this correct?**

No, two different evaluation plans are not required. There is a note following the guidance on the Evaluation and Performance Measurement Plan in the “Application and Submission Information” section to advise applicants that addressing the items identified for the plan under the “CDC Project Description” section meets the requirement for the plan described in the “Application and Submission Information” section.

22. **The FOA provides a sample format for a PE plan which includes listed activities for each objective. Would these activities be different than the ones in our program narrative and work plan, or are they just more in depth?**

The sample format provides a simplified and standardized template to prepare the PE plan. The work plan should outline the activities that your program will carry out to meet national and state program objectives in correlation with the seven strategies outlined in the logic model. Performance towards achieving targets for national and state program objectives as measured through the NTIP system is historically reported in the project narrative (completion of therapy (COT), for example). One to three priority areas can be selected for in-depth program evaluation based on the performance data. The evaluation plan consists of questions, measures, and outcomes related to this in-depth evaluation.

23. **The HRD plan is a separate attachment, correct?**

No, the Human Resource Development (HRD) plan is not a separate submission. The HRD plan is submitted as part of the project narrative. Strategies for HRD are described in the project narrative, and the work plan contains training activities and the HRD plan.

24. **Page 32 of the FOA - Strategy and Activities: section iv. refers us to the community guide for evidence-based program strategies. There isn't a TB section listed in the guide. Is there a place I should be looking, or are we just supposed to be using the specific 7 TB strategies given in the FOA?**

Applicants should use the seven strategies in the FOA.

25. **Since the scoring under the Application review Information section (pgs. 41-45) were developed under the intent of an objective panel, but applications are now going to be reviewed under a structured technical review; is there a different scoring template we should be aware of?**

No, the scoring listed in the FOA will be used for the structured technical reviews.

- 26. Reference the guidance on attachments under the “Other Information” section of the FOA; can the work plan be uploaded as an attachment instead of within the page count of the project narrative?**

The work plan can be uploaded along with the project narrative as a single submission labelled “project narrative” or as a separate upload labelled “work plan”. In either instance the work plan counts as part of the 30-page limit for the project narrative. The information on attachments under the “Other Information” section is meant to provide a comprehensive listing of acceptable attachments or “submissions” discussed earlier in the FOA.

- 27. What is rationale for the specific activities required by morbidity level? Is the implied assumption that states/cities in tiers 1 will not prioritize evaluation of immigrants and refugees? Who will be responsible for this activity if not the TB programs? Similarly, is the implication that state/big cities/jurisdictions in tiers 1 and 2 will not ensure targeted testing and treatment for TB?**

This FOA was developed to accommodate declining resources, thus a priority-based approach was utilized. It is understood that programs take a graduated approach in applying their TB P&C strategies according to their overall success of their activities. The activities associated with each tier reflect those that should be completed at minimum. There is no restriction on programs attempting to complete activities associated with a higher tier, provided the minimum expectations are met for their tier.

- 28. How do the priorities listed on the Priority Table on page 9 relate to the activities listed under the strategies beginning on page 10? Are programs expected to address all of the priorities and strategy activities in to project narrative?**

The lead paragraph under each strategy (beginning on page 10) identifies the P&C priority to which it’s linked, or how it supports program evaluation, HRD, and laboratory activities. Programs are expected to address all applicable priorities, strategies, and activities in their project narrative.

- 29. Most programs will have achieved a combination of activities addressed in all three “tiers” regardless of morbidity level. Since it would not make sense to abandon priorities in Tier 3 if successful, although morbidity might make you a Tier 2 program how do you want that addressed?**

As long as Tier 1 or Tier 2 programs can successfully implement priority 1 and 2 activities (respectively), they are encouraged to pursue priority 3 activities, but not until the higher priority activities are achieved, starting in Tier 1, then Tier 2.

30. What is the total funding amount for US states and cities?

The total anticipated funding for all eligible programs funded through the cooperative agreement in 2015, based on availability of funds, is \$77,120,123 (see #4 under Award Information).

31. What is the total funding amount for US territories?

See response to question #30.

32. What is the funding amount for each jurisdiction?

See response to question #30.

33. If a jurisdiction questions the funding amount allocated to the program based on the funding formula, what mechanism exists to review the computations?

Jurisdictions can contact their program consultant after NOAs have been issued for clarification on how the funding amount was determined for their jurisdiction. In 2012, DTBE provided information on the components, methodology, and timeline for the implementation of the formula, as well as other decisions made by the funding formula workgroup. This information was shared in multiple Dear Colleague letters and will be resent to all TB programs.

34. The increase in activities requested is made with a decrease in funds, how are these activities expected to be implemented given funding reductions?

It is not clear which activities in the current FOA are viewed as an increase over prior year's expectation; however, the intent of the FOA's priority-based approach is to afford programs greater flexibility to meet requirements within the limits of their resources.

35. Why was the amount for US programs decreased?

The overall funding amount projected for 2015 based on availability of funds is level with the overall final amount awarded in 2014.

36. What will allow an increase in funds if there is a need by a jurisdiction going forward?

Though it would not be correct to say it allows for increase in funds, the new FOA does allow programs to submit "true needs" budgets for both P&C and laboratory that anticipate the amount needed for operational costs, program improvement initiatives, and potential emergencies. If, in their budget submission, a program made a justifiable request for more funds than the formula determined, such budget could be approved with certain amounts deferred. The deferred amounts could be

funded (if needed) should funds be available at a later date and the request approved.

- 37. What is the proposed process for requesting a review of the implications of the full funding formula implementation? In light of the apparent decrease of the total dollars available to distribute the funding formula, as currently designed, seems to further penalize low morbidity states?**

Such a review of the funding formula should include DTBE, NTCA and representatives from low, medium, and high incidence jurisdiction. DTBE is open to discussions on future reviews of the funding formula.

- 38. Can we use the turnaround time for results from molecular testing (e.g., pyrosequencing or GeneXpert) as part of the calculation to determine the following performance value: “Report percent rifampin results reported for initial diagnostic specimens within 17 days of identification of MTBC from culture.”?**

You can no longer use molecular test results to address the value for this performance indicator. With the change in how the indicator is measured (i.e., time from identification from culture), applicants must use data from conventional drug susceptibility testing.

- 39. In compiling the budget, is it appropriate to include supplies for conventional drug susceptibility testing as part of the true needs section of the budget until such time that a regional laboratory begins accepting specimens for DST?**

Yes, it would be acceptable to include a request for these supplies as part of the true needs section of the budget for a limited time period but not as part of the anticipated line-item request.

- 40. If our laboratory performs testing for another state funded, in part, by the TB Elimination and Laboratory Cooperative Agreement, should we include data for that state in our application?**

No, please only include data specific for your state reflective of results you would report to your local TB Program (i.e., not research projects). The state for which you are performing testing would provide their data in their application.

- 41. Should the laboratory component use the structure for the project narrative as described on page 32 of the FOA?**

Yes, the laboratory component should include a brief project narrative that reflects the structure as described in the announcement along with a work plan providing more specific information relative to anticipated outcomes.

42. **Can the organizational chart be included as an attachment or is it considered as part of our 8 page limit?**

The organizational chart is an acceptable attachment and is not considered as part of the 8-page limit for the laboratory component.

43. **In our laboratory, we receive sediments where another laboratory has set up the culture. We perform a molecular test that provides information confirming the presence of Mycobacterium tuberculosis complex as well as the genotypic drug results. Can we count these in our tally of NAA tests performed?**

Yes, it is acceptable to include the per patient count from referred sediments for NAA testing in the workload indicator 5 and 5a (for positive results) as described on page 23 of the FOA.

44. **In cases where a local laboratory sets up the culture, and then sends us remaining sediment for molecular detection of mutations associated with drug resistance, can these be counted as part of our workload indicator for the number of patients for whom drug susceptibility testing is performed?**

No, as written in the FOA on page 23, please only include data for growth-based drug susceptibility testing.

45. **What is meant by growth-based MTBC first-line DST on page 23 of the FOA? Can we include drug susceptibility testing that we perform for referred isolates?**

The term growth-based is used to differentiate conventional drug susceptibility testing from molecular tests (e.g., DNA sequencing or GeneXpert). Yes, you can include data for referred isolates that your laboratory examines.