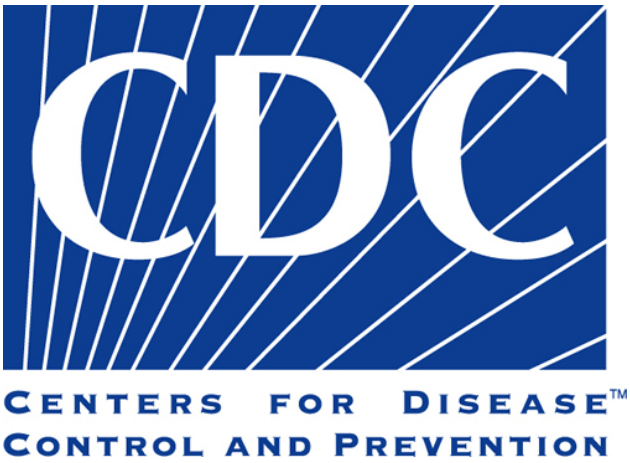

Centers for Disease Control and Prevention

NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD AND TB PREVENTION

Tuberculosis Elimination and Laboratory Cooperative Agreement

CDC-RFA-PS-25-0003

10/04/2024

Table of Contents

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-PS-25-0003. 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) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Tuberculosis Elimination and Laboratory Cooperative Agreement

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For purposes of this NOFO, research is defined as set forth in 45 CFR 75.2 and, for further clarity, as set forth in 42 CFR 52.2 (see eCFR :: 45 CFR 75.2 -- Definitions and *https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf*. In addition, for purposes of research involving human subjects and available exceptions for public health activities, please see 45 CFR 46.102(l) (*https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102(l)*).

New-Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS-25-0003

E. Assistance Listings Number:

93.116

F. Dates:

1. Due Date for Letter of Intent (LOI):

2. Due Date for Applications:

10/04/2024

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:

The TB Elimination and Laboratory informational call will be conducted on Friday, July 12, 2024, from 2:00 p.m. – 3:30 p.m. Eastern Standard Time. The webinar link is:

You are invited to a Zoom webinar.

When: July 12, 2024, 02:00 PM Eastern Time (US and Canada)

Topic: 2025 TUBERCULOSIS ELIMINATION AND LABORATORY INFORMATIONAL CONFERENCE CALL

Register in advance for this webinar:

https://cdc.zoomgov.com/webinar/register/WN_1oAfD_UgQXaSMttTu9wXww

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 160 381 5459

Passcode: 58271256

SIP: 1603815459@sip.zoomgov.com

Passcode: 58271256

After registering, you will receive a confirmation e-mail containing information about joining the webinar.

Note: Participants must register in advance of the call date(s) to participate.

Frequently Asked Questions will be made available on the Division of Tuberculosis Elimination website: TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

G. Executive Summary:

1. Summary Paragraph

The Tuberculosis Elimination and Laboratory Cooperative Agreement Notice of Funding Opportunity (NOFO) CDC-RFA-PS-25-0003 is being re-announced for a limited time. It has been brought to our attention that in some instances, attachments A and B did not successfully upload when applications were submitted. **If the attachments were NOT successfully submitted with your application, you have the opportunity to re-submit your application**

with the two attachments. Applicants that successfully included attachments A and B in their prior application are not required to re-submit.

Attachments A and B are described as follows. Refer to page 36 of the NOFO for a complete description:

Attachment A: TB Prevention, Control and Elimination Plan--A plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought. Summary of a plan, including laboratory activities, must be included.

Attachment B: Evidence of Jurisdiction Infrastructure-Summary of jurisdiction's ability to conduct TB disease surveillance, report surveillance data to CDC, respond to outbreaks, contain emerging disease threats, conduct disease investigation, intervention, and follow-up as well as those performing laboratory testing.

Failure to upload the required documents will deem the application non-responsive.

This announcement is open September 27—October 4, 2024.

If there are any questions, please contact NOFO POC Martha Boisseau at mrb0@cdc.gov.

a. Funding Instrument Type:
CA (Cooperative Agreement)

b. Approximate Number of Awards
57

c. Total Period of Performance Funding:
$374,456,055

d. Average One Year Award Amount:
$1,313,880
Of special note: The actual range of individual awards is **$142, 891 to $8,717,737** and are based on a funding estimator. The funding for prevention and control is allocated using a formula approach to ensure equitable distribution of resources based on changing TB epidemiology and program performance. A fixed funding amount is allocated for Human Resource Development based on the TB incidence level in each project area. Laboratory funding is allocated using a workload-based formula approach to ensure equitable distribution of resources.

e. Total Period of Performance Length:
5 year(s)

f. Estimated Award Date:
December 01, 2024

g. Cost Sharing and / or Matching Requirements:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this Notice of Funding Opportunity (NOFO) exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Tuberculosis (TB) disease is caused by *Mycobacterium tuberculosis*, an airborne pathogen that spreads from person to person. An estimated one fourth of the world's population is infected with *M. tuberculosis* and 5-10% of those infected persons develop TB disease in their lifetime. In 2022, 10.6 million people around the world became sick with TB disease. Globally, TB is a leading cause of death: in 2022, there were 1.3 million TB-related deaths world-wide. TB is the leading killer of people living with human immunodeficiency virus (HIV). A total of 8,331 TB cases (a rate of 2.5 cases per 100,000 persons) were reported in the United States in 2022. After declining 20% in 2020, concurrent with the COVID-19 pandemic, TB incidence rates increased by 9.6% in 2021 and a further 5.5% in 2022. Current strategies alone will not achieve TB elimination in the United States in this century. Meeting the TB elimination goal will require a focus on testing and treating persons at higher risk of latent TB infection (LTBI) to prevent TB disease. Up to 13.0 million people in the United States have LTBI and over 80% of the TB cases result from LTBI that was not treated.

TB disproportionately affects certain populations, including persons who are non-U.S.-born, who have HIV infection or diabetes, who are experiencing homelessness, who are incarcerated, or who misuse substances such as alcohol or certain drugs. Non-U.S.-born persons had 73.8% of the cases in the United States in 2022: the incidence rate among non-U.S.-born persons in 2022 was 17.1 times greater compared to the rate among U.S.-born persons.

This NOFO supports finding and curing persons with TB disease and following up on exposures to TB. It includes targeted testing for preventing TB by finding and treating LTBI among groups such as the non-U.S.-born.

CDC is continuing its 40-year approach of funding priority activities in TB programs through cooperative agreements (CoAgs). Officials in health departments are responsible for TB control and prevention activities and laboratory services under the statutes and regulations of states, cities, or territories. This funding should complement those efforts. It is not intended to replace or reduce state and local investment in priority activities and responsibilities such as diagnosing and treating TB, providing inpatient care, tracing contacts, finding, and treating LTBI, and managing health department clinics.

b. Statutory Authorities

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

c. Healthy People 2030

This NOFO addresses the Healthy People 2030 Immunization and Infectious Diseases topic area.

For more information, visit Reduce tuberculosis cases — IID17 - Healthy People 2030 | health.gov

d. Other National Public Health Priorities and Strategies

- National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Strategic Plan –

  NCHHSTP Strategic Priorities | CDC NCHHSTP

- Division of Tuberculosis Elimination Strategic Plan 2022-2026-DTBE

  Tuberculosis Elimination Priorities | CDC NCHHSTP

- National Action Plan for Combating Multidrug-Resistant Tuberculosis –

  National Action Plan for Combating Multidrug-Resistant Tuberculosis | Document | U.S. Agency for International Development (usaid.gov)

- U.S. National Strategy for Combating Antibiotic-Resistant Bacteria –

  U.S. Actions & Events to Combat Antimicrobial Resistance | Antimicrobial Resistance | CDC

- National Stakeholder Strategy for Achieving Health Equity –

  National Stakeholder Strategy for Achieving Health Equity

e. Relevant Work

This NOFO builds on the accomplishments achieved through past CDC TB prevention and control (P&C) and laboratory strengthening Cooperative Agreements (CoAgs), which contributed to the reversal of TB resurgence in the U.S. during 1985–1992, 2021 and 2022. The earlier resurgence was driven in part by budget cuts, loss of program capacity, growing incidence of HIV infection, and transmission of multidrug-resistant TB (MDR TB) in hospitals and other settings, the latter resurgence by the COVID-19 pandemic. Current and previous CDC TB CoAgs have reinforced the downward U.S. TB incidence trends of the past 40 years.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

-

Strategies and Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Diagnosis and treatment of persons with TB disease • Advise providers on TB diagnosis and treatment • Manage cases and ensure	• **Increased use of Nucleic Acid Amplification Testing (NAAT)** • Decreased time between symptom onset and diagnosis • **Increased cases with HIV and**	• Earlier patient diagnoses • **Increased patients completing treatment within 12 months** • Decreased acquired drug resistance	• **Decreased TB incidence overall and among populations at higher risk**

treatment adherence • Promote infection control	**drug susceptibility testing results** • **Increased patients on and responding to appropriate treatment** • **Increased use of appropriate drug regimens matched to DST results**	• Decreased TB recurrence • Decreased patient infectious period • Decreased TB transmission	• Decreased TB mortality • Decreased LTBI prevalence • Elimination of TB disease in the United States • Decreased contacts who progress from infection to disease • Increased health equity related to TB/ LTBI testing and treatment strategies • Increased ability to maintain program capacity toward TB elimination • Increased availability of well-trained and informed public health practitioners, laboratorians, and health providers with knowledge and experience to accurately diagnose, treat, and prevent TB
Conduct contact investigations for infectious TB cases • Elicit, examine, test, and treat contacts with TB infection	• **Increased contacts elicited** • **Increased contacts examined** • **Increased treatment initiation and completion among contacts with LTBI started on LTBI treatment**	• **Increased LTBI treatment completion among contacts**	
Test and treat populations at higher risk for TB and LTBI • Select and conduct targeted testing among population(s) at higher risk for TB/ LTBI • Engage TB control program and local community organizations to reach populations at higher risk for TB/ LTBI and provide effective and culturally appropriate services	• **Increased identification, testing, and treatment of persons at higher risk for developing TB** • Increased networks and coalitions with local community groups, clinics, and primary care providers to effectively diagnose and treat TB/LTBI, to advance equity and share information about TB/ LTBI • **Increased follow-up medical examinations and**	• Increased treatment initiation and completion among persons in high-risk populations diagnosed with TB / LTBI • Established and maintained networks and coalitions between partners and local communities that experience high TB incidence and LTBI prevalence • **Improved access to medical and social services through partnerships to**	

• Examine immigrants and refugees with Class B notificatio**n**	**treatment initiation for persons with LTBI and prior pulmonary TB who are recommended for treatment**	**address TB/ LTBI disparities**	
Program planning, monitoring, evaluation, and improvement • Conduct program evaluation and implement remediation activities to improve performance • Implement TB elimination plans • Establish contingency plans to manage drug shortages and distribution issues	• Increased implementation of TB elimination plans • Increased identification and dissemination of best practices by state and local TB programs • Increased development and implementation of contingency plans to manage drug shortage and distribution issues.	• Increased programs meeting national TB performance targets • Increased use of findings to inform policy changes • Increased ability to manage drug shortages and distribution issues	
Surveillance • Report TB cases in a timely, accurate, and complete manner • Link genotype results to surveillance records in a timely and complete manner • Routinely review TB genotype clusters and prioritize investigation and public health action	• Increased accuracy and completeness of surveillance data • Increased verified TB cases reported to CDC ≤1 week • Increased culture-confirmed cases with ≥1 isolate genotyped and linked to surveillance data • Increased capacity for timely and thorough cluster and outbreak identification and investigation	• Increased use of epidemiologic analyses of surveillance data to inform TB elimination activities • Reduced cluster- and outbreak-associated transmission • Increased standardized (voluntary) case-level surveillance for LTBI	

• Promote standardized collection and reporting of case-level LTBI surveillance data • Report on contacts to cases and persons who were part of targeted testing among populations at higher risk	• Increased local programs collecting standardized case-level LTBI data • Increased capacity and readiness to report core case-level LTBI surveillance data to CDC • **Increased timely submission of annual contact investigation and targeted testing data through the Aggregate Reports for Tuberculosis Program Evaluation**		
Human resource development (HRD) and partnerships • Develop and implement HRD plans • Collaborate with organizations and providers serving high-risk populations	• Increased availability and accessibility of culturally sensitive and competency-based education and training • Increased awareness and use of HRD resources • Increased levels of TB awareness and knowledge among patients, providers, and communities	• Increased capacity to diagnose and treat high-risk populations in culturally sensitive manner • Increased adoption of new technologies for TB/ LTBI treatment • Increased efficiency of laboratory operations, based on implementation of evidence-based policies and procedures and enriched collaborations	
Laboratory strengthening • Use laboratory data to address or evaluate methods, algorithms, and testing needs of	• **Increased samples meeting recommended turnaround times for core TB laboratory services, either**		

populations served • Ensure availability of high-quality and timely core TB laboratory services • Collaborate with partners to serve patient populations	**through in-house testing or referral** • Increased use of laboratory data to evaluate and inform testing practices • Increased awareness of availability and accessibility for TB testing services		

i. Purpose

This NOFO will aid current state, local, and territorial TB program efforts to prevent, control, and eliminate TB in the United States by ensuring national geographic coverage and prioritizing jurisdictions with the highest TB disease burden. Funds will enhance state and local investments in TB prevention and control activities; the development of human resources through improved training, education, communications, and information dissemination; and strengthen laboratory capacity to ensure that timely, reliable TB laboratory services are available to health care providers and TB programs.

ii. Outcomes

By the end of this 5-year period of performance, NOFO recipients must address all short-term, intermediate, and long-term outcomes in the logic model, and achieve all the outcomes highlighted in bold-type in the logic model.

Short Term Outcomes:

- Increased use of Nucleic Acid Amplification Testing (NAAT)
- Increased cases with HIV and drug susceptibility testing results
- Increased patients on and responding to appropriate treatment
- Increased use of appropriate drug regimens matched to DST results
- Increased contacts elicited
- Increased contacts examined
- Increased treatment initiation and completion among contacts with LTBI started on LTBI treatment
- Increased identification, testing, and treatment of persons at higher risk for developing TB
- Increased follow-up medical examinations and treatment initiation for persons with LTBI and prior pulmonary TB who are recommended for treatment

- Increased timely submission of annual contact investigation and targeted testing data through the Aggregate Reports for Tuberculosis Program Evaluation
- Increased samples meeting recommended turnaround times for core TB laboratory services, either through in-house testing or referral

Intermediate Outcomes:

- Increased patients completing treatment within 12 months
- Increased LTBI treatment completion among contacts
- Improved access to medical and social services through partnerships to address TB/ LTBI disparities

Long Term Outcome:

- Decreased TB incidence overall and among populations at higher risk

Recipients should achieve these outcomes in alignment with current National TB Program Objectives and Performance Targets found at

http://www.cdc.gov/tb/programs/evaluation/indicators/default.htm and

National TB Laboratory Turnaround Time Performance Targets found at

Cooperative Agreement Toolkit (aphl.org)

iii. Strategies and Activities
Strategy 1: Diagnosis and treatment of persons with TB disease

To accomplish the priority activity of identifying individuals with presumptive 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 using adherence-promoting measures such as case review/cohort analysis, outreach staff who are culturally competent, extensive application of conventional and electronic directly observed therapy (DOT, and eDOT), incentives, and enablers. The recipient is responsible for case management and treatment for all persons with active TB currently residing in the recipient's jurisdiction regardless of the person's permanent legal residence.
- Provide drug shortage contingency plan— Drug shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. To develop a drug shortage contingency plan, programs will need to engage the highest levels of leadership at the department level, legal and procurement to obtain support for procurement contingencies including but not limited to contracting with alternate distributers, accessing anti-TB drugs from other programs within the state or a region, and arranging drop shipments directly from manufacturers, and notifying the Food and Drug Administration (FDA) and the National Tuberculosis Coalition of America (NTCA)

of drug shortages. The drug shortage contingency plan may not rely on obtaining drugs from the CDC stockpile.

- 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 U.S. Centers for Disease Control and Prevention guidelines. Refer to the following web link for more information: Treatment for Latent TB Infection and TB Disease | TB | CDC
- Seek expert consultation for treatment of multidrug-resistant TB (MDR TB) and other complex cases from TB experts who are up-to-date on current evidence-based practices and guidelines, and who are readily available to provide timely documented advice and ongoing medical guidance. CDC's TB Centers of Excellence (COE) for Training, Education, and Medical Consultation services should be readily used as needed, and relationships should be fostered between any local TB experts who provide the program with clinical guidance and the funded jurisdictions' regional COE. Healthcare providers of record for patients with TB disease should be expected to be familiar with laboratory and chest imaging results as well as current medications and comorbidities when seeking additional medical consultation services.
- For each patient for whom COE services are sought, TB programs will identify a licensed physician or other licensed health care provider with prescriptive authority who assumes responsibility for providing appropriate care for the patient as the healthcare provider of record within the recipient jurisdiction responsible for case management and treatment.
- Seek expert consultation regarding laboratory results for molecular detection of drug resistance or interpretation of other laboratory results when needed. Refer to the following web links for more information:

  Tuberculosis Laboratories | Tuberculosis (TB) | CDC

  Molecular Detection of Drug Resistance (MDDR) in Mycobacterium tuberculosis Complex by DNA Sequencing User Guide | Tuberculosis (TB) | CDC

  https:// www.cdc.gov/tb-programs/php/about/tb-coe.html

  https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Training-Modules.aspx

- Collaborate with HIV and STD 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 treated to completion.
- Use, promote, and disseminate effective bi-national 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 Health (DGMH) to support international and bi-national TB quarantine efforts.
- Establish a process to review case management activities routinely to ensure optimal patient care.
- Develop a TB elimination plan for the new period of performance (2025-2029). A summary of the plan should be submitted with this application. If funded, a complete plan should be submitted by the end of year one. This plan should be developed and implemented with ongoing collaboration with a TB elimination advisory committee.

Strategy 2: Conduct contact investigation for infectious TB cases.

To implement this strategy, recipient will conduct the following activities:

- Interview persons with TB and utilize location-based methods to identify contacts and evaluate them and to make sure that infected contacts begin and complete LTBI treatment.

  Treatment for Latent TB Infection and TB Disease | TB | CDC

- Assess reasons for cases with no contacts elicited, for delays in interviewing cases or examining contacts, and for lower 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 a more robust database for contact investigation should continue to make improvements to the data collection instrument and ensure data are used to inform progress on TB control and prevention.

- It is highly encouraged that staff conducting contact investigations attend a TB COE contact investigation interviewing skills course.

Strategy 3: Test and treat populations at higher risk for TB and LTBI.

All programs must work on the following activities:

- Select and conduct targeted testing among population(s) at higher risk for TB/ LTBI. Ensure that effective interventions are implemented to identify non-U.S.–born and

locally-determined populations at greater risk for developing TB, and that they are evaluated and treated for TB and LTBI if recommended. Refer to the following web link for more information on treatment recommendations for LTBI: Treatment Regimens for Latent TB Infection | TB | CDC

- Establish a baseline for testing individuals identified at higher risk of having LTBI and/or progressing to TB disease and identify a goal and strategy for scaling-up targeted testing for LTBI.

- Establish a baseline for initiating and completing treatment for individuals diagnosed with LTBI who are recommended for treatment and identify a goal and strategy for increasing LTBI treatment initiation and completion rates.

- Engage TB control program and local community organizations to reach populations at higher risk for TB/ LTBI and provide effective and culturally appropriate services. Populations at higher risk for LTBI and/or progression to TB disease should be locally defined. Definition should be based on epidemiological data, and may include but not be limited to persons who: have medical risks such as HIV; have end-stage renal disease; are non-U.S.-born and from countries with high rates of TB as defined by the World Health Organization, including persons reported by civil surgeons; have substance use disorders; are health care workers; are homeless; or have been incarcerated. Collaborating with community partners is encouraged, such as working with homeless shelters to capture the TB screening and treatment outcomes.

- Establish partnerships with HIV, diabetes, and/or other non-communicable disease program staff (e.g., smoking, alcohol abuse) to promote testing for LTBI 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.

For more information, please see these links:

TB and Diabetes | TB | CDC

TB Risk and People with HIV | Tuberculosis (TB) | CDC

National Library of Medicine

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2945809/

- Partner with primary care providers serving under-resourced communities to expand LTBI testing and treatment.

- Report targeted testing and treatment data using the Aggregate Reports for Tuberculosis Program Evaluation (ARPE) using the Targeted Testing and Treatment of Patients with Latent TB Infection form.

- Examination of immigrants and refugees with TB or LTBI. Ensure that immigrants and refugees classified as Class A or B are located promptly and examined and treated appropriately: http://www.cdc.gov/immigrantrefugeehealth/

- Report examination results of domestic TB follow-up activities including treatment outcomes for TB and LTBI to the Electronic Disease Notification (EDN) system: https://www.cdc.gov/immigrant-refugee-health/php/case-reporting-edn/index.html

Strategy 4: Program planning, monitoring, evaluation, and improvement

Program evaluation helps demonstrate achievement of project outcomes, builds a stronger evidence base for specific interventions, and drives continuous program improvement through planning and implementation of remediation strategies. Recipients are expected to conduct program evaluation to improve performance and demonstrate progress toward achieving the short, intermediate, and long-term outcomes in the logic model.

Recipients must design and implement program evaluation activities that address TB indicators aligned with National TB Objectives where national performance targets are not met by the recipient. In all cases, CDC reserves the right to assign program evaluation topics that advance the goal of national TB elimination.

Each recipient is required to identify a program evaluation focal point. The designated program evaluation focal point will be responsible for the following:

- Serve as the point of contact for program evaluation activities in their jurisdiction.
- Provide leadership and serve as a resource for building program evaluation capacity within their jurisdiction.
- Share program evaluation experiences and lessons learned with partners and colleagues.
- Work closely with CDC TB program staff, including program evaluation consultants.
- Participate in TB Program Evaluation Network (PEN) activities including bimonthly conference calls. The focal point shall attend the TB ETN (Education and Training Network)/PEN biennial conference. TB CoAg funds can be used to support travel for the appointed TB program evaluation network focal point to attend the TB ETN/PEN conference.

For more information, please see this link:

https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm

Strategy 5: Surveillance

This strategy requires timely assessment and reporting of all confirmed TB cases; prompt detection and investigation of and response to possible TB outbreaks; and identification of surveillance infrastructure gaps and system needs. Recipients are expected to:

- Enhance identification, reporting, and follow-up of persons with confirmed or presumptive TB by establishing collaborative relationships with appropriate reporting sources including:
    - Hospitals and clinics (e.g., TB, HIV, and STD clinics)
    - Laboratories performing testing for mycobacteria
    - Healthcare providers (e.g., pulmonary and infectious disease sub-specialists)
    - Correctional facilities
    - Homeless shelters
    - Community and migrant health centers
    - Pharmacies
    - State and local Social Services agencies
    - Other public and private facilities providing care to populations at risk for TB

- Ensure complete, accurate, and timely reporting of persons with confirmed or presumptive TB by:
    - Maintaining TB disease as a mandatory reportable condition as required by state and local laws.
    - Increasing awareness among healthcare providers and laboratorians of the requirement to report TB cases.
    - Maintaining a surveillance data collection system that includes all data elements contained in the current version of the Report of Verified Case of TB (RVCT).
    - Conducting active surveillance for TB because of a known or suspected outbreak or when there is reason to believe that passive surveillance is insufficient to identify all cases of TB.
    - Ensuring that testing and reporting of comorbid conditions associated with TB (e.g., HIV, diabetes, viral hepatitis) is provided for all persons with TB disease at time of diagnosis.
    - Following CDC data security and confidentiality guidelines: Data Security & Confidentiality | Program Collaboration and Service Integration | CDC
    - Assuring surveillance data quality by:
        - Creating, maintaining, and regularly updating a TB surveillance quality assurance protocol that is available to CDC upon request.
        - Available resources include:

            Quality Assurance for Tuberculosis Surveillance Data-A Guide and Toolkit for 2013:

            ftp.cdc.gov - /pub/Software/TIMS/2009 RVCT Documentation/RVCT Training Materials/Quality Assurance Materials/

- Participating in regular data quality review meetings.
- Routinely reviewing and addressing data quality issues identified through the National Tuberculosis Surveillance System (NTSS) Reports and other systems.
- Conducting other activities as needed.

- Notifying CDC of TB cases in a complete, accurate, and timely manner by:
    - Maintaining an electronic data system for verified TB cases that is compatible with the National Notifiable Disease Surveillance System (NNDSS) standards.
    - Reporting complete and accurate data on all verified TB cases to CDC using the current RVCT.
    - All TB case notification messages to CDC should be transmitted via NNDSS or another CDC-approved system.
    - All verified TB cases should be reported to CDC regardless of whether the cases are considered "countable" in official case counts.
    - All RVCT data elements should be filled out completely according to CDC instructions for the RVCT: Report of Verified Case of Tuberculosis Instruction Manual | Tuberculosis (TB) | CDC.
    - Ensuring all TB case notification messages to CDC are transmitted within 1 week for newly verified cases and within 1 month for previously verified cases with updated information.
    - Ensuring that all RVCT data for a TB case, including treatment completion and outcome information, are submitted to CDC within 2 years of the initial case report.

- Ensure genotype results are linked to surveillance records in a timely and complete manner by:
    - Submitting *one of* the following within 8 weeks of culture confirmation:
        - At least one isolate from persons with culture-positive TB to a CDC-designated laboratory for genotyping, *or*
        - A sequence read set (i.e., the data from whole-genome sequencing of *M. tuberculosis* isolates) to CDC that meets CDC quality specifications.
    - Linking genotyping results to surveillance data as soon as possible and within 8 weeks of genotype results becoming available, either through the TB Genotyping Information Management System (TB GIMS) or by entering the genotyping laboratory accession number in the appropriate field on the RVCT.
    - Regularly review TB genotype clusters and prioritize investigation and public health action:
    - Ensure prompt identification and investigation of TB genotype clusters by:
        - Reviewing genotype clusters within 1 week of receiving notification.
        - Collaborating with CDC to investigate TB genotype cluster alerts generated by the TB Genotyping Information Management System (TB GIMS) to determine whether a TB outbreak is occurring.

        - Ensure appropriate response to clusters determined to be outbreaks by:
        - Conducting timely and appropriate epidemiologic investigation of, and response to, TB outbreaks.
        - Providing reports at initial detection, and quarterly thereafter, of outbreak investigation and response activities, including epidemiologic data and ongoing or planned interventions to control transmission.
        - For large outbreaks (≥10 cases diagnosed in a 3-year period that are related by recent transmission) identified by molecular surveillance or programmatic activities, these reports should include:
            - A line list of state case numbers associated with the outbreak, selected based on molecular or epidemiologic data.
            - Epidemiologic linkages identified among cases.
            - Results of contact investigations, including TB and LTBI treatment outcomes.
            - Confirmation of which cases are involved in large outbreaks, based on molecular or epidemiologic data.
            - Descriptions of the outbreak settings (e.g., homeless overnight facilities).
            - Barriers to outbreak investigation and control (e.g., patients not seeking care despite experiencing TB symptoms for long periods).

- Promote standardized collection and reporting of case-level LTBI surveillance data by:
    - Evaluating what steps are needed to make LTBI a reportable condition in the recipient's jurisdiction (for those jurisdictions where LTBI is not already reportable).
    - Conducting a needs assessment and gap analysis to establish what actions need to be taken to implement case-level LTBI surveillance using the Tuberculosis Latent Infection Surveillance System (TBLISS).
    - **If feasible**, submitting an LTBI surveillance plan to the CDC by the end of the performance period.
    - **If feasible**, provide data on case-based surveillance for LTBI by:
        - Collecting data on all contacts of infectious TB patients who are diagnosed with LTBI consistent with data elements contained in TBLISS.
        - Collecting data on all persons diagnosed with LTBI in public health department clinics consistent with data elements contained in TBLISS and according to the CDC TBLISS Instruction Manual (available upon request).
        - Transmitting LTBI case notification messages via NNDSS or other CDC-approved system for all verified LTBI cases to CDC in a timely manner.

Strategy 6: Human Resource Development (HRD) and Partnerships

The goal of TB Human Resource Development (HRD) is to strengthen the capacity of TB programs and other partners to prevent and control TB through improved training, education,

communications, and information dissemination. As part of this strategy, recipients are expected to work on the following:

- Develop and implement HRD plans
    - Designate a focal point for training and education within the TB program. This person should be (or become) a member of the TB 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 CDC and COE education and training activities, including needs assessments, capacity building, and resource development/sharing.
    - Ensure development and implementation of annual training and HRD activities specific to their TB program.
    - Provide an annual update of progress-to-date on HRD activities in the performance report.
    - Attend the biennial focal point meeting and the biennial TB ETN conference.
    - Identify training and HRD needs.
    - Provide competency-based in-service TB training and human resource development.
    - Establish evaluation strategies to improve existing training and to identify ongoing training and HRD needs.

Improve patient education and communications capacity within the program. Collaborate with organizations and providers serving high-risk populations, including:

- Coordinating training related to TB control with training for other disease control interventions, such as HIV, viral hepatitis, and STD.
- Targeting TB training to other health care providers or organizations serving high-risk populations.

Strategy 7: Laboratory Strengthening

This strategy ensures the availability of high quality and timely core laboratory services for TB, the ability to address or evaluate laboratory methods, algorithms, and testing needs for patient populations served, and to collaborate with partners. This is accomplished by public health laboratories through the following:

- Ensuring availability of reliable, timely laboratory services and use of growth-based and molecular methodologies for the detection of, isolation of, identification of, and susceptibility testing for *M. tuberculosis* complex (MTBC) appropriate to the individual laboratory's workload and experience
    - Resources:
        - Clinical and Laboratory Standards Institute (CLSI) Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes. 3rd ed. CLSI standard M24.

    - Clinical and Laboratory Standards Institute (CLSI) Performance Standards for Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes. 2nd ed. CLSI standard M24S.
    - Clinical and Laboratory Standards Institute (CLSI) Laboratory Detection and Identification of Mycobacteria. 2nd ed. CLSI guideline M48.
    - Technical Report on Critical Concentrations for Drug Susceptibility Testing of Medicines Used in the Treatment of Drug-resistant Tuberculosis. Geneva: World Health Organization; 2018.
    - Technical Report on Critical Concentrations for Drug Susceptibility Testing of Isoniazid and the Rifamycins (Rifampin, Rifabutin, and Rifapentine). Geneva: World Health Organization; 2021.
    - Catalogue of Mutations in *Mycobacterium tuberculosis* Complex and Their Association with Drug Resistance. Second edition. Geneva; World Health Organization; 2023.

- Increasing the proportion of samples meeting recommended turnaround times (TAT) for core TB laboratory services, either through in-house testing or referral.
- Ensuring that testing methods and algorithms selected are the most effective for workload volume of specimens received and laboratory capacity.
- Processing fewer than 15 specimens per week (the recommended minimum level of activity to maintain proficiency) in a laboratory should prompt consideration of referral to another laboratory. Performing first-line drug susceptibility testing (DST) for <50 patient isolates per year should prompt consideration of referral of isolates to the National DST Reference Center or another laboratory Self-Assessment Tool (aphl.org).
- Ensuring access to nucleic acid amplification testing (NAAT) for rapid detection of MTBC directly from clinical specimens.
- Ensuring mutations detected by probe-based methods (i.e., *rpoB* mutations detected by Xpert® MTB/RIF) are confirmed by DNA sequencing.
- Ensuring laboratory algorithms for referral testing are developed, used, and include submission requirements for CDC'S Molecular Detection of Drug Resistance (MDDR) Service and reference center(s) used for DST and additional molecular testing (including genotyping).
- Ensuring that at least one isolate from all persons with culture-confirmed TB is genotyped (using whole genome sequencing either in-house or through referral) in a timely manner for national molecular surveillance efforts.
- Supporting, as applicable, the use of interferon gamma release assays (IGRA) to aid in diagnosing *Mycobacterium tuberculosis* infection.
- Using laboratory-specific data to guide decisions regarding testing algorithms, improving TAT, laboratory services, and business practices for gained efficiencies and rapid reporting of results.
- Implementing when practical, state-of-the-art technologies and approaches to improve service offerings and decrease TAT.
- Strengthening collaboration with partners, including TB Programs, clinicians, TB nurses, CDC Laboratory Consultants, and other laboratories, to ensure optimal use of laboratory services and timely flow of information.

1. Collaborations

a. With other CDC projects and CDC-funded organizations:

Collaborations should exist between recipients and the CDC-funded TB Centers of Excellence for Training, Education, and Medical Consultation (COEs) Tuberculosis Centers of Excellence for Training, Education, and Medical Consultation | Information for Tuberculosis Programs | CDC. The COEs provide training to TB program staff on topics including TB and LTBI clinical diagnosis and treatment, program management training, supervisor training, contact investigations, case management, TB laboratory information for non-laboratory personnel, and program evaluation.

Collaborations should also exist between TB and HIV-funded recipients at the state and local levels.

b. With organizations not funded by CDC:

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

- Private providers;
- Correctional facilities;
- 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;
- State and local social services agencies;
- AIDS Education and Training Centers;
- Substance Abuse and Mental Health Services Administration (SAMSHA);
- Addiction Technology Transfer Centers;
- Refugee resettlement assistance agencies and
- Indian Health Service and Tribal Organizations.

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

- Each recipient 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 (e.g., correctional facilities, including federal bureau of prisons and immigrations and customs facilities, homeless shelters, etc.)

- Each recipient will collaborate with HIV and STD 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. Rapid HIV testing should be offered to patients in TB clinics.

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

  High Quality Care: Access and Delivery | High Quality Care | CDC

- Recipients are encouraged to collaborate with US Immigration and Customs Enforcement (ICE) officials to implement processes to ensure coordination of TB patients discharged from healthcare facilities in accordance with applicable state laws or regulations:

  2011 Operations Manual ICE Performance-Based National Detention Standards

  2019 National Detention Standards for Non-Dedicated Facilities | ICE

  Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws

- Recipients are encouraged to communicate with Health Care for the Homeless Council as potential partners to address TB control among the homeless:

  Tuberculosis - National Health Care for the Homeless Council (nhchc.org)

- Recipients are encouraged to collaborate on training with HIV, STD, and viral hepatitis training partners and to integrate disease content as appropriate in courses to increase collaboration and service integration. Go to the following link for more information:

  Program Collaboration Service Integration | Program Collaboration and Service Integration | CDC

- Recipients 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:

  340B Drug Pricing Program | HRSA

- Recipients are encouraged to collaborate with other laboratory professionals (state, local, clinical, commercial) and laboratory organizations including the Association of Public Health Laboratories (APHL).

  APHL

- Memoranda of Understanding (MOUs)/ Memoranda of Agreement (MOAs) are not required for the NOFO but are strongly recommended if a TB program determines that formalization of collaboration is needed with an organization. Submit MOUs/MOAs as attachments with NOFO application.

It is strongly recommended that relevant TB program staff attend the CDC Program Manager's course (local public health staff should attend a COE TB Control Program Manager's Course).

2. Population(s) of Focus

Targeted efforts to diagnose and complete treatment of TB in populations at higher risk for TB exposure and progression will help prevent TB transmission, reduce TB-associated mortality, and promote TB control. Targeted efforts to test and treat latent TB infection (LTBI) will reduce TB incidence in populations at higher risk for LTBI and TB, which will ultimately reduce TB disparities and improve health equity in such populations. Targeted TB prevention and control efforts should focus on the following populations:

- All persons with TB disease
- Persons having recent contact to infectious TB, especially children younger than 5 years of age
- Non-U.S.-born persons from countries with elevated TB rates who reside in, or are traveling to, the United States
- Racial and ethnic minority populations who are at greater risk for TB infection
- Persons living with HIV and others who are immunosuppressed
- Persons with diabetes and additional TB risks
- Persons working or residing in congregate settings (e.g., correctional facilities, homeless shelters)
- Persons with substance use disorders (i.e., excess alcohol use, injection-drug use, non-injection-drug use)
- Persons aged 65 or older
- Persons with multiple medical and social risk factors

Among the populations identified above, applicants should strive to be inclusive of people with limited health literacy, non-English speaking or limited English-speaking populations, persons with mental health disorders or problems, or other people who are medically or economically underserved in the population of focus that the program may miss.

Applicants should propose specific strategies to reach, test, and treat these populations. Data collection and analysis to assess progress on targeted testing and treatment efforts by population would be helpful to describe the scope and successes of these efforts. TB fact sheets, language resources, culturally appropriate patient education materials, and other resources are available through TB Centers of Excellence:

> Tuberculosis Centers of Excellence for Training, Education, and Medical Consultation | Information for Tuberculosis Programs | CDC

and the following websites:

Health Disparities in TB

> Health Disparities in Tuberculosis | Tuberculosis (TB) | CDC

Find TB Resources

> Find TB Resources | CDC FTBR and

Racial and Ethnic Approaches to Community Health (REACH)

About REACH | REACH | CDC.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

a. Health Disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Broadly defined, social determinants of health are non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. See content below and in other sections (e.g., Approach, Collaborations, Populations of Focus) for information on how this specific NOFO affects social determinants of health.

A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

A health disparity occurs when the TB incidence or outcome is greater or lesser among certain population groups compared with others. Health disparities are often linked to a complex blend of economic and social conditions that influence the health of individuals, communities, and jurisdictions. Social determinants are the economic and social conditions that influence the health of individuals, communities and jurisdictions and include conditions for early childhood development; education, employment, and work; food security, health services, housing, income,

and social exclusion. Beyond individual-level factors that contribute to health disparities, programs should consider the social needs and structural drivers of inequities (e.g., income, housing, employment, food security, etc.). TB adversely affects populations that have historically experienced greater obstacles to health based on their national origin, racial or ethnic group, age, medical, social, or physical condition (e.g., HIV, substance use disorder, homelessness). For example, the percentage of TB cases that occur in Asians, Blacks or African Americans, Hispanics, American Indians or Alaska Natives, and Native Hawaiian or other Pacific Islanders is higher than expected based on the percentage of these minorities in the U.S. population. To achieve TB elimination, ongoing efforts must address the persistent disparities that exist.

Recipients should identify strategies and describe activities that will support efforts to improve the health of populations disproportionately affected by TB/LTBI. Programs should use available data to identify disproportionately affected communities within their jurisdictions; In collaboration with partners and appropriate sectors of the community, programs should conduct program-specific evaluations, and use culturally appropriate interventions, that are tailored to the communities for which they are intended. These strategies and activities should maximize programmatic impact by reducing disease incidence, improving outcomes, and advancing health equity.

See the following links:

Social Determinants of Health (SDOH) at CDC | About CDC | CDC

Health Disparities in Tuberculosis | Tuberculosis (TB) | CDC

Communicating About Health Equity Concepts | Health Equity | CDC

Health Equity Guiding Principles for Inclusive Communication | Gateway to Health Communication | CDC

iv. Funding Strategy

CDC will use a funding formula for the Prevention and Control (P&C), Human Resources Development (HRD), and Laboratory components of the Cooperative Agreement (CoAg) that is built on years of experience and collaboration with multiple public health partners. CDC distributes TB CoAg funds according to a case-based formula for P&C and HRD, and a workload-based funding formula for the laboratory. Furthermore, performance indicators are included within the P&C formula e.g., 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. This strategy aligns the funding with the changing TB epidemiology in the United States. For guidance on the funding strategy, see Section 12, the Budget Narrative section.

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 based on availability of funds to provide the appropriate supplemental award needed to support emergency outbreak responses.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC will monitor recipients' performance by assessing the following:

- progress toward reaching the national performance target for each National TB Program Objective,
- information included in annual performance report

Standardized performance measures established in the National TB Indicators Project (NTIP) National TB Program Objectives and Performance Targets for 2020 | Mission Statement and Activities | About Us | TB | CDC will be used for calculating process and outcome indicators. NTIP uses data recipients report through the National TB Surveillance systems (NTSS), TB Genotyping Management system (TB GIMS), the Aggregate Report for Program Evaluation (ARPE), and the Electronic Disease Notification System (EDN) to calculate and generate indicator reports.

CDC will work with recipients to manage and analyze NTIP data to assess recipient program improvements, respond to broader technical assistance needs, and report to stakeholders. CDC will develop performance measurement reports from NTIP and disseminate to recipients and other key stakeholders, including federal partners, other funded and non-funded partners, and policy makers, as appropriate. These findings may also be presented during site visits and recipient meetings.

For recipient-led evaluations, CDC will monitor the development and implementation of program evaluation activities and the application of program evaluation findings in promoting progress towards reaching national performance targets and reducing health disparities.

CDC will monitor recipients' performance by assessing progress towards reaching National Tuberculosis Laboratory Performance Targets for specimen receipt, acid-fast bacillus (AFB) smear, nucleic acid amplification, identification (ID), growth-based and molecular sequencing drug susceptibility testing (DST), and interferon gamma release assays (Cooperative Agreement Toolkit (aphl.org)). CDC Laboratory Consultants will engage with recipients to provide technical assistance, to assess performance measure progress and obstacles, and to develop educational opportunities related to strengthening the TB laboratory and its staff. CDC will develop a biennial Tuberculosis Laboratory Aggregate Report and laboratory-specific data sheets for each recipient. These data along with workload, testing algorithms, staffing, and laboratory methods will be reviewed and discussed during in-person or virtual site visits to inform use of laboratory-specific data.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement, including, as applicable to the award, how findings will contribute to reducing or eliminating health disparities and inequities.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).
- How evaluation findings will be disseminated to communities and populations of interest in a manner that is suitable to their needs.
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additional-requirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Evaluation and Performance Measurement – Programmatic Focus

Applicants must submit a TB Program Evaluation Plan for the first year that describes the process the applicants will use to increase their understanding of factors contributing to their performance. Performance measures for National TB Program Objectives are outlined under the National TB Indicators Project (NTIP). Applicants will use NTIP indicator reports to identify programmatic areas in need of improvement, develop program evaluation plans to determine why the program is not meeting national performance targets for NTIP indicators, and develop remediation strategies to improve performance. NTIP indicators are available at the following link:

National TB Program Objectives and Performance Targets for 2025

The TB Program Evaluation Plan for the first year should include the following information:

A. Background

- Describe the rationale for selecting the program evaluation focus area (identify which NTIP indicator or other data source was used to determine the focus area and why this area was chosen).
- Describe how the applicant intends to use findings and the expected impact on the program.

B. TB Program Evaluation Plan

- Define the evaluation objectives and\or key evaluation questions. Each objective should be Specific, Measurable, Achievable, Realistic and Time-bound (SMART).
- For each program evaluation objective, describe the methods and timelines for data collection and analyses.

C. TB Cohort Review Plan

- Describe how the applicant will implement TB Cohort Review to perform systematic reviews of case management activities. It is understood that applicants may have different approaches at systematically reviewing their case management activities and program performance. The designated TB program evaluation focal point person can consult with the DTBE program evaluation consultant of the respective area to develop the plan.
- Additional information on conducting cohort reviews is also published in the CDC resource, "Understanding the TB Cohort Review Process: An Instruction Guide" Understanding the TB cohort review process; an instruction guide (cdc.gov).
- If the applicant is not meeting the national targets for multiple National TB Program Objectives, they shall conduct a program evaluation related to a minimum of one of these targets per budget period. In all cases, CDC reserves the right to assign program evaluation topics that advance the goal of national TB elimination.

Applicants should identify and implement remediation strategies to improve performance as part of their evaluation activities. A description of these remediation strategies should be included in reporting the results of the program evaluation.

Each applicant will be responsible for describing their program evaluation results from the program evaluation plan outlined the prior year and the remediation strategies identified to promote performance improvement.

Evaluation and Performance Measurement – Laboratory Focus

The narrative for the laboratory component should address the following:

Laboratory Element 1: Ensure availability of high-quality and timely core TB laboratory services.

All laboratories, regardless of volume, should provide a work plan on laboratory activities related to improving each of the National TB laboratory turnaround time (TAT) performance targets. Report on the following information:

- Laboratory-specific measurable goals for improving each TAT indicator (specimen receipt, acid-fast bacilli [AFB] smear, nucleic acid amplification test [NAAT], identification [ID], growth-based drug susceptibility testing [DST], molecular sequencing DST, and interferon gamma release assay).
- Laboratory-specific goals should be chosen to strive to achieve or exceed national targets.
- If the laboratory is currently meeting national targets, maintaining the current TAT or a new measurable goal should be listed.

- Specific strategies and activities for achieving the stated goals.
    - Laboratory workload volume and TAT data (use Performance Progress and Monitoring Report Forms A and D) forms are available for use at TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

An Excel work plan is available for use:

TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

Current performance targets and instructions on how to calculate TATs can be found at:

Cooperative Agreement Toolkit (aphl.org)

Laboratory Element 2: Laboratories, regardless of volume, should provide **at least two measurable objectives** and related strategies for Element 2.

To improve laboratory efficiency and quality assurance during the 5-year period of performance, laboratory-specific data should be monitored, frequently reviewed, and analyzed to explore opportunities for process improvements. Laboratories should strive for continual quality improvement (e.g., workload and turnaround numbers/percentages over time, testing algorithms, contamination rate, equipment improvements/challenges). Report on the following information:

- Measurable objectives to improve efficiency and quality assurance for your laboratory.
- Specific strategies and activities related to improvements.
- Target completion date/timeline and measure of success.

Laboratory Element 3: Laboratories, regardless of volume, should provide **at least two measurable objectives** and related strategies for Element 3.

Laboratories will communicate and collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

Laboratories could initiate plans for increased communication or educational opportunities, promote evidence-based practices, partner on electronic ordering and reporting systems, and collaborate with TB Programs and clinical laboratories to improve awareness and understanding of laboratory services (e.g., development of specimen collection guidelines or promotion of available in-house or reference laboratory services). Report on the following information:

- Measurable objectives to improve communication and collaboration with partners for your laboratory.
- Specific strategies and activities to improve communication and collaboration.
- Target completion date/timeline and measure of success.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants must have the organizational capacity to develop, implement, and manage the work necessary for a TB program and TB laboratory and demonstrate the ability to execute the strategies and activities, and meet stated outcomes successfully (see Eligibility Section). The primary responsibility for designing and carrying out TB prevention and control activities rests with state and local health departments, not the Federal Government.

Applicants should:

- describe their state or local TB program(s), including infrastructure, workforce competence, data systems, and electronic information systems.
- provide evidence of adequate program management, planning and development of policy, performance measurement, workforce development and training, and capacity to manage the required priority driven activities.
- briefly demonstrate the capacity to manage persons who have presumptive or active TB, including provision of clinical care with appropriate medications, medical consultative services, and infection control and coordination with other healthcare providers.
- confirm their ability to provide or refer TB patients for inpatient care and confinement if required.
- discuss their diagnostic methods for case finding and contact investigation, including laboratory and chest radiographic services.
- describe their ability for managing persons with LTBI.
- confirm their TB case reporting process, including appropriate laws and regulations to support TB control activities, surveillance, and TB registry.
- describe their data collection and analysis processes; and demonstrate adequate protection of confidentiality.
- describe strategies and activities to address TB disparities among disproportionately affected populations.

- provide an organizational chart of personnel performing TB laboratory testing including names of staff in each position including those funded through TB Cooperative Agreement funding.
- provide a brief description of the test methods used in the laboratory, including those for specimen processing, direct detection, AFB smear, culture, identification, growth-based DST, molecular sequencing DST, whole genome sequencing [WGS] (for clinical and/or surveillance purposes), genotyping, and interferon gamma release assay (IGRA). Include a brief overview of the overall laboratory testing workflow or algorithm. (a visual testing algorithm can be included as an attachment).
- identify designated focal points for education and training, program evaluation, and laboratory, including their contact information and description of their roles and responsibilities.

d. Work Plan

Applicants are required to provide a work plan that provides both a high-level overview of the entire five-year performance period and a detailed description of the first year of the award. No specific work plan format is required, if it is clear how the components in the work plan crosswalk to the strategies and activities, outcomes, and evaluation and performance measures presented in the logic model and the narrative sections of the NOFO. Therefore, the work plan should demonstrate how activities will be executed, to achieve the outcomes for the following strategies:

- Diagnosis and treatment of persons with TB disease
- Conduct contact investigations for infectious TB cases
- Test and treat populations at higher risk for TB and LTBI
- Program planning, monitoring, evaluation, and improvement
- Surveillance
- Human resource development (HRD) and partnerships
- Laboratory strengthening

At a minimum, TB program work plans should include the following elements:

- Related desired outcome
- Related outcome measure
- Breakdown of activities
- Related process measure for each activity
- Position or party responsible for each activity
- Target completion date/frequency for each activity.

To view an example of a TB program work plan, please visit the TB NOFO Resource webpage at:

TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

Public Health Laboratory Strengthening

Public health laboratory narrative should include an organizational chart with staff members (including those funded through the CoAg), a designated point of contact (name, telephone number, and email), and description of testing methods. A laboratory testing algorithm may be included within the narrative, or a visual testing algorithm may be included. The public health

laboratory work plan should address Laboratory Elements 1, 2, and 3 as described below. Refer to the Glossary for an explanation of laboratory terms.

- **Laboratory Element 1:** Ensure availability of high quality and timely core TB laboratory services.
- **Laboratory Element 2:** Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data.
- **Laboratory Element 3:** Communicate and collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

Please ensure the laboratory work plan and workload volume and TAT data forms are included. The Excel file and PDFs are available using the link below:
TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient 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 deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

CDC’s post monitoring activities will also include:

- Aiding recipients in tracking and evaluating the progress toward reaching stated outcomes and National TB Program Objectives
- Providing technical assistance and consultation to public health laboratories regarding timely and reliable laboratory testing and reporting of laboratory data.

- Conducting conference calls with TB program, laboratory staff and CDC Project Officers along with other relevant project personnel as needed to assist in successful implementation of proposed activities.
- Encouraging participation in webinars and recipient meetings and/or yearly reporting on successful program implementation for TB notes article.

Ensuring follow-up discussion of the feedback with appropriate program staff and CDC stakeholders, including program, Program Evaluation (PE), and laboratory consultants within a given timeline (e.g., 30 days).

f. CDC Program Support to Recipients

In a Cooperative Agreement, CDC staff members are substantially involved in the program activities beyond routine grant monitoring during the period of performance. CDC's support beyond monthly calls, site visits, and regular performance and financial monitoring will include:

- Aiding with collaborative activities with other services and organizations (e.g., Centers of Excellence [COEs], private providers, community health centers [CHCs], federally qualified health centers [FQHCs]).
- Providing consultation through the CDC TB Health Equity Workgroup on initiating and maintaining activities to address health equity issues.
- 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 recipient 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 period of performance.

Human Resource Development

CDC activities for this component 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 biennial TB ETN conference or via consultation with CDC after award of funds.

- Conducting a focal point meeting at the biennial TB ETN/TB PEN conference.
- Directing the COEs to coordinate regional on-site training courses (e.g., TB Contact Investigation Interviewing Skills course, Effective TB Interviewing for Contact Investigation course, or Program Managers course) 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 component are as follows:

- Contribute to the improvement of public health laboratory performance by providing technical assistance.
- Identify training needs and collaborate with partners to develop courses, webinars, workshops, and training materials for distribution to public health laboratories.
- Provide consultation for the development and implementation of laboratory performance indicators and data analysis methods for laboratory internal quality assurance programs.
- Assist in the development and dissemination of best practice guidelines and recommendations for the implementation of cost-effective testing algorithms.
- Support laboratory performance evaluation by providing a biennial aggregate report of workload data and TAT performance measures from laboratories receiving funding assistance to be used to compare one's laboratory to national TB laboratory data.

B. Award Information

1. Funding Instrument Type:
CA (Cooperative Agreement)
CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:
U52 CDC-RFA-PS-25-0003 Tuberculosis Elimination and Laboratory Cooperative Agreement

3. Fiscal Year:
2025

4. Approximate Total Fiscal Year Funding:
$74,891,211

5. Total Period of Performance Funding:
$374,456,055
This amount is subject to the availability of funds.

Estimated Total Funding:
$374,456,055

6. Total Period of Performance Length:

5 year(s)

year(s)

7. Expected Number of Awards:
57

8. Approximate Average Award:

$1,313,880
Per Budget Period

Of special note: The actual range of individual awards is **$142, 891 to $8,717,737** and are based on a funding estimator. The funding for prevention and control is allocated using a formula approach to ensure equitable distribution of resources based on changing TB epidemiology and program performance. A fixed funding amount is allocated for Human Resource Development based on the TB incidence level in each project area. Laboratory funding is allocated using a workload-based formula approach to ensure equitable distribution of resources.

9. Award Ceiling:
$0
Per Period of Performance

This amount is subject to the availability of funds.

10. Award Floor:
$0
Per Period of Performance

11. Estimated Award Date:
December 01, 2024

12. Budget Period Length:
12 month(s)

Throughout the period of performance, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (period of performance) 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 period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance
Direct Assistance (DA) is available through this NOFO.

Direct Assistance (DA) is available through this NOFO.

Applicants may request federal personnel, medication from the TB Emergency Drug Stockpile (TEDS) [during emergency situations] and equipment, or supplies as Direct Assistance (DA).

Applicants may also convert Financial Assistance (FA) to DA for host-site travel for federal personnel.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

2. Additional Information on Eligibility

Government Organizations:

- Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, and the Virgin Islands.

Non-government Organizations:

Other:

In accordance with the statutory authority provided in Section 317E(d) of the PHS Act (42 USC 247b-6(d)):

The applicant must provide evidence that they have the necessary public health infrastructure and authority to conduct TB disease surveillance; report TB surveillance data to CDC; respond to TB outbreaks; contain emerging TB disease threats; conduct TB disease investigation, intervention, and follow-up and perform TB laboratory testing for the eligible project area for which funding is sought.

The applicant must upload two attachments in the application entitled Attachment A- “TB Prevention and Control Elimination Plan” and Attachment B- “Evidence of Jurisdiction Infrastructure” that includes the following two documents:

1. TB Prevention, Control and Elimination Plan--A plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought. Summary of a plan, including laboratory activities, must be included.
2. Evidence of Jurisdiction Infrastructure-Summary of jurisdiction's ability to conduct TB disease surveillance, report surveillance data to CDC, respond to outbreaks, contain emerging disease threats, conduct disease investigation, intervention, and follow-up as well as those performing laboratory testing.

Required documents must be uploaded as Attachment A and Attachment B under Appendix A. Failure to upload the required documents would deem the applicant non-responsive.

The applicant cannot request an award greater than the anticipated budget formula for the project area.

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this Notice of Funding Opportunity (NOFO) exists, 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

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.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number associated with your organization's physical location prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned through SAM.gov registration. Some organizations may have multiple UEI numbers. Use the UEI number associated with the location of the organization receiving the federal 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 a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). 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 can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" 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 should start the registration process as early as possible.

	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	1. Go to SAM.gov and create an Electronic Business Point of Contact (EBiz POC). You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	7-10 Business Days but may take longer and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an account in Grants.gov, then add a profile by adding the organization's new UEI number. 2. The EBiz POC can designate user roles, including Authorized Organization Representative (AOR).	Allow at least one business day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

		3. AOR is authorized to submit applications on behalf of the organization in their workspace.		

2. Request Application Package

Applicants may access the application package at www.grants.gov. Additional information about applying for CDC grants and cooperative agreements can be found here: https://www.cdc.gov/grants/applying/pre-award.html

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) 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 OGS.

a. Letter of Intent Deadline (must be emailed)

b. Application Deadline

Due Date for Applications 10/04/2024

10/04/2024
11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Information Conference Call
The TB Elimination and Laboratory informational call will be conducted on Friday, July 12, 2024, from 2:00 p.m. – 3:30 p.m. Eastern Standard Time. The webinar link is:

You are invited to a Zoom webinar.

When: July 12, 2024, 02:00 PM Eastern Time (US and Canada)

Topic: 2025 TUBERCULOSIS ELIMINATION AND LABORATORY INFORMATIONAL CONFERENCE CALL

Register in advance for this webinar:

https://cdc.zoomgov.com/webinar/register/WN_1oAfD_UgQXaSMttTu9wXww

Or an H.323/SIP room system:

H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)

Meeting ID: 160 381 5459

Passcode: 58271256

SIP: 1603815459@sip.zoomgov.com

Passcode: 58271256

After registering, you will receive a confirmation e-mail containing information about joining the webinar.

Note: Participants must register in advance of the call date(s) to participate.

Frequently Asked Questions will be made available on the Division of Tuberculosis Elimination website: TB Elimination and Laboratory Cooperative Agreement Funding | Information for Tuberculosis Programs | CDC

5. Pre-Award Assessments

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

N/A

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

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, Word, or Excel file format under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

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.

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. 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 period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

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

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the period of performance, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the period of performance. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Population(s) of Focus and Health Disparities

Applicants must describe the specific population(s) of focus in their jurisdiction and explain how to achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Population(s) of Focus and Health Disparities requirements as described in the CDC Project Description, including (as applicable to this award) how to address health disparities in the design and implementation of the proposed program activities.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see https://www.cdc.gov/os/integrity/reducepublicburden/index.htm.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).

- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

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 recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. 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:

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

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000.

Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation or reaccreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), 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 American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver essential public health services and ensure foundational capabilities are in place, such as activities that ensure a capable and qualified workforce, strengthen information systems and organizational competencies, build attention to equity, and advance 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 NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. These goals may include supporting vital records offices participating in the Vital Records and Health Statistics Accreditation Program, certifying vital records offices to meet industry standards. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; provide financial assistance to support accreditation related fees and/or support staff time to coordinate accreditation activities; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and can upload it as a PDF, Word, or Excel file format at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the 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 Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

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

Funding estimate calculator for TB programs and laboratories is provided on the TB resources page on the CDC internet at https://www.cdc.gov/tb-programs/php/funding/elimination-and-laboratory-cooperative-agreement.html to assist applicants with completing their detailed budget for the first year of funding under this NOFO. The funding estimator provides applicants an estimate of their total award based on data from their jurisdiction for the reporting periods used

in determining funding for 2025. The funding estimators are under the section "Funding by category" - the user needs to click to expand to see the estimators.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Employee Whistleblower Rights and Protections

Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, “Enhancement of contractor protection from reprisal for disclosure of certain information” and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC’s Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient’s submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient’s submitting author must also post the manuscript through PMC within twelve (12)

months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16. Funding Restrictions

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

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - 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 anti-lobbying restrictions for CDC recipients.
- 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.

Special instructions for HRD and laboratory funding:

Human Resource Development (HRD): Include a line-item budget to specify how funds will be used to achieve program-specific HRD objectives and activities as stated in this document; seek guidance from CDC as needed.

HRD funds are intended to provide training and education of TB program staff. For example, it is strongly recommended that relevant TB program staff attend the CDC program managers course (local public health staff should attend a COE TB Control Program Managers' Course). It is highly encouraged that staff conducting contact investigations attend a COE contact investigation interviewing skills course. Using HRD funds for training external to the TB program (e.g., National Jewish Health Clinical Course) should be limited to courses that are not delivered by the respective TB program or COE as determined by course content and job responsibilities of the participant. TB programs can also request that their COE conduct specific trainings in their state.

Also, HRD funds can be used to support travel for TB training and education staff to attend the TB ETN/PEN conference. Using HRD funds to attend other conferences should be discussed in advance with each recipient's program consultant.

Public Health Laboratory Strengthening: Include a line-item budget to specify how funds will be used to achieve laboratory-specific objectives and activities as stated in this document. Laboratories from states with low numbers of TB cases or performing first-line DST for less than 50 patient isolates/year may not request funding support for reagents and supplies associated with DST. Laboratories within this category may request the use of funds for shipping supplies and costs for access to referral services such as those available at the National DST Reference Center for *Mycobacterium tuberculosis*. Seek guidance from your laboratory consultant as needed.

Restrictions for public health laboratories:

- Laboratories performing first-line DST for less than 50 patient isolates/year should consider referral of isolates to a reference laboratory for testing such as the National PHL DST Reference Center. National PHL DST Reference Center (aphl.org)
- Laboratories from states with low numbers of TB cases or reporting less than 50 patient isolates/year may not request funding support for reagents and supplies associated with 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.

Other restrictions:

The use of Cooperative Agreement funds for hospitalization, construction, and the purchase of medications is prohibited.

Recipients may not use funds for inpatient clinical care.

Additionally:

Recipients 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.

17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additional-requirements/ar-25.html.

18. Intergovernmental Review

You will need to submit application information for intergovernmental review under Executive Order 12372. Under this order, states may design their own processes for obtaining, reviewing, and commenting on some applications. Some states have this process and others don't.

To find out your state's approach, see the list of state single points of contact. If you find a contact on the list for your state, contact them as soon as you can to learn their process. If you do not find a contact for your state, you don't need to do anything further. This requirement never applies to American Indian and Alaska Native tribes or tribal organizations.

19. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. Application attachments can be submitted using PDF, Word, or Excel file formats. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

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 two 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 NOFO. 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 review the Applicants section on www.grants.gov.

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@grants.gov. Application submissions sent by e-mail 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 e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail 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 www.grants.gov 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 received via e-mail to the GMS/GMO listed below 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, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

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

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

NOFO reviewers will follow CDC's merit review process by evaluating eligible and responsive applications in accordance with the criteria below. Reviewers may be external to the federal government (non-federal personnel), federal personnel, or a mix of federal and non-federal personnel.

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant's Organizational Capacity to Implement the Approach

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

i. Approach

Maximum Points: 50

i. Approach	**Maximum Points:** 50
Evaluate the extent to which the applicant conforms to the following: • **TB Prevention, Control and Elimination Plan:** (3 points) Applicant includes a plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought. Summary of a plan must be included. • **Problem Statement:** (1 point) Applicant adequately described the core information relative to the public health problem to understand how the application response to the NOFO 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**: (1point) 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, those submitting for laboratory testing, and others in their jurisdiction.	

- **Target populations**: (3 points)

Applicant identified target populations in their jurisdiction and addressed how they will include specific populations who can benefit from the program. These include all persons with TB disease; non-U.S. 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 determinants of health.

- **Outcome: (5 points)**
    - Application adequately described the period of performance outcomes the applicant intends to achieve 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 adopt available state-of-the art technologies (diagnostics & treatment) effectively and efficiently, and improved use of local data for greater effectiveness and transparency.
    - HRD - Improved ability of TB program staff to translate knowledge and skills into practice.
    - Laboratory – Improvement of each of the National TB laboratory TAT performance targets, gained laboratory efficiencies and improved quality assurance using laboratory-specific data, and increased communication and collaboration with partners.

- **Strategies and Activities**: (5 points)

Applicant provided clear and concise description of the strategies and activities that will be used to achieve period of performance outcomes.

- P&C - The application described which of the tiers applied to the jurisdiction based on the definition in the NOFO, and the appropriate priority level program activities identified in the NOFO that will be employed to achieve period of performance outcomes.
- HRD - Individual identified to serve as the focal point for training and education, and clearly described their duties and responsibilities. The application described how the training and human resource development activities will accomplish the strategies listed in the NOFO.
- Laboratory - The application adequately described laboratory activities outlined in the NOFO including how the laboratory would ensure improvements in national TB TATs, gained laboratory

efficiencies and improved quality assurance through the use of laboratory-specific data, and increased communication and collaboration with partners.

- **Work plans for Prevention and Control (P&C)**: (15 points)

Work plans for P&C must at minimum address the following:

- Specify priority level to be used for period of performance and its alignment with the program strategies.
- Describe activities within selected priority level for the period of performance and related objectives, milestones, and intended outcomes with timelines, and they must be in alignment with chosen priority and program strategies, as well as the logic model.
- 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., non-U.S.--born persons, homeless shelters, correctional facilities, other congregate settings).
- Include monitoring and evaluation plan for milestones accomplishing during the period of performance.
- Describe administration and assessment process to ensure successful implementation and quality assurance.
- Describe staff and administrative roles and functions to support implementation of the NOFO.
- Describe plan for addressing TB drug shortages that does not rely on obtaining drugs from the CDC stockpile.
- Specify the name and responsibilities of the clinician serving as the state or local TB medical consultant for the jurisdiction. In circumstances where the number of cases of TB is very low **and** a state or local TB medical consultant is not available, describe how the program plans to liaison licensed outpatient clinicians caring for TB patients *as the provider of record* within the recipient jurisdiction responsible for case management and treatment, and contacts to their regional TB COE, and how program will support this partnership.

- **Work Plan for 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. Describe the applicant's plan to:

- Identify training and HRD needs.

o Provide competency-based in-service TB training and human resource development. o Establish evaluation strategies to improve existing training and to identify ongoing training and HRD needs. o Improve patient education and communications capacity within the program. o Coordinate training related to TB control with training for other disease control interventions, such as HIV, viral hepatitis, and STD. o Target TB training to other health care providers or organizations serving high-risk populations. **By the end of year one, provide the following information to be used in a national TB workforce assessment:** a. A list of current positions with titles and percent Full Time Equivalent (FTE), both filled and vacant. b. A list of additional desired positions with titles and percent FTE believed necessary to fully execute the program's elimination plan. • **Work Plan for Public Health Laboratory Strengthening: (10 points)** The Work Plan must address the following: o Identify a laboratory point of contact with title, e-mail address, and phone number. o Provide an organizational chart with TB personnel listed; indicate staff that are funded through the TB Cooperative Agreement funding. o Provide a brief description of laboratory testing methods. o Include a laboratory testing workflow or algorithm (a visual testing algorithm can be included as an attachment). The Work Plan must include the following: o Complete workload volume and TAT data forms. o A description of strategies and activities for meeting defined objectives for each Laboratory Element. o **Element 1:** Ensuring availability of high-quality and timely prompt core TB laboratory services. o **Element 2:** Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data. o **Element 3:** Communicate and collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely information flow.	

ii. Evaluation and Performance Measurement

Maximum Points: 25

Evaluate the extent to which the applicant addresses the items below.

- How complete is the application in describing the Performance Measurement Strategies as described in the NOFO (See Page 5-6, CDC Project Description.)? **(10 points)**
- How complete is the application in describing the Performance Measurement Plan to achieve the outcomes as described in the NOFO (See CDC Project Description)? **(10 points)**

Includes a preliminary Data Management Plan (DMP), if applicable. **(5 points)**

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points: 25

Evaluate the extent to which the applicant:

- Summarizes the jurisdiction's ability to perform TB prevention and control activities including conducting TB laboratory testing and TB diagnostics; treatment for TB and latent TB infection; TB disease surveillance and reporting TB surveillance data to CDC; responding to TB outbreaks; containing emerging disease threats – specifically as related to TB; conducting TB disease investigation, TB intervention(s), and TB follow-up, as well as confirming continuity of TB prevention and control activities with those performing TB laboratory testing and/or reporting TB cases. **(5 points)**
- Describes how the program is organized, the nature and scope of its work and/or the capabilities it possesses. **(2.5 points)**
- Describes experiences and successes in conducting TB prevention and control activities, including development and successful implementation of Program Evaluation (PE) plan, especially aimed at targeted populations. **(5 points)**
- Provides a laboratory organizational chart with designated laboratory point of contact (indicate staff that are funded through TB Cooperative Agreement funding), TB testing methods performed, laboratory TB testing workflow algorithm, and laboratory workload volume and TAT data forms. **(5 points)**
- Describes how staff competencies will be assessed and develop a plan to address gaps through organizational and individual training and development opportunities. **(5 points)**

Demonstrates experience and capacity to coordinate with tribal governments and/or tribally designated organizations in their jurisdiction, if applicable. **(2.5 points)**

Budget

Maximum Points: 0

CDC Project Officers will evaluate the extent to which the budget aligns with the proposed work plan and the anticipated awarded amount using the TB funding formulas.

Applicants will be notified electronically no later than 30 days after Phase II review is completed if their application does not meet eligibility or submission requirements.

c. Phase III Review

CDC will conduct merit reviews of applications and provide feedback to all applicants. Applicants will be selected based on a panel assessment of the applicant's organizational capacity to implement the approach. CDC may fund out of rank order based on any of the following criteria, using the best available data at the time.

1. To ensure complete national geographic coverage;
2. Jurisdictions with the highest number of TB disease cases.

CDC will provide justification for any decision to fund out of rank order.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207. CDC's review of risk may impact award eligibility.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Additionally, we may ask for additional information prior to the award based on the results of the CDC's risk review.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Awards will be announced via electronic copy of the Notice of Award (NoA) from CDC Office of Grants Services (OGS) on December 1, 2024.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions (June 2012)

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

AR-14: Accounting System Requirements

AR-20: Conference Support

AR-21: Small, Minority, And Women-owned Business

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-27: Conference Disclaimer and Use of Logos

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-32: Enacted General Provisions

AR-34: Language Access for Persons with Limited English Proficiency

Brief descriptions of relevant provisions are available at https://www.cdc.gov/grants/additional-requirements/index.html.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

3. Reporting

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

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance 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 NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

a. Recipient Evaluation and Performance Measurement Plan (required)
With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

• Performance measures and targets
• The frequency that performance data are to be collected.
• How performance data will be reported.
• How quality of performance data will be assured.
• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching specific populations or achieving expected outcomes).
• Dissemination channels and audiences.
• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publicly available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)
The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**

- Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

- **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.

Within the 65-page limit of the APR, recipients should use a maximum of

- 40 pages for P&C;
- 10 pages for HRD; and
- 15 pages for Laboratory Strengthening

to cover performance reporting and the funding application. Applicants are allowed more than the 45 pages outlined in the instructions.

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

- In BP 2025, the APR will be due August 31 for the activities performed January 1, 2025, through June 30, 2025.
- For BPs 2025 - 2029, APRs will be due on August 31 of each year. Each APR 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.

Note: To meet CDC requirements for this NOFO, reports should include performance and outcome reporting specific to each component as follows:

Prevention and Control (P&C):

- 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 objectives.
- Report on the priority level activities highlighting successful outcomes, including developing benchmarks for specific activities.
- 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?
- Report on specific strategies and collaborations related to addressing co-morbidities and health disparities.

Program Planning, Evaluation, and Improvement:

- Annually, each applicant\recipient will be responsible for describing their program evaluation results from the program evaluation plan outlined the prior year, the remediation strategies identified to promote performance improvement, and with their program evaluation plan for the coming year. The program evaluation annual report must include the following:
    - Results and Conclusions of the prior years' program evaluation activities:
        - Describe status of implementation of the program evaluation plan, including rationale for plan revisions and barriers and facilitators to plan completion.
        - Report findings, including barriers, facilitators and lessons learned, related to reaching performance targets.
        - Discuss limitations that may have affected the evaluation's findings.

- Remediation Plan based on the prior year's program evaluation activities:
    - Describe how findings and lessons learned will be applied to improve program performance.
    - Identify plans to share findings and lessons learned to promote program improvement (i.e. presentations, reports, webinars, conferences, publications).
    - Outline a plan and timeline to evaluate the effectiveness of the remediation.

- Background for the coming years' program evaluation focus area:
    - Describe the rationale for selecting the program evaluation focus area (identify which NTIP indicator or other data source was used to determine the focus area and why this area was chosen.
    - Describe how the applicant intends to use findings and the expected impact on the program.
        - Program Evaluation Plan for the coming year
        - Define the evaluation objectives and\or key evaluation questions. Each objective should be Specific, Measurable, Achievable, Realistic and Time-bound (SMART).
        - For each program evaluation objective, describe the data sources, methods and timelines for data collection and analyses.

- Annually, each applicant\recipient must identify their Designated Program Evaluation Focal Point, including the following information:
    - Name:
    - Job title:
    - Mailing address:
    - Telephone:
    - FAX number:
    - E-mail:

- 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 training	

Human Resource Development:
Recipients should report on progress of HRD activities and achievements for the previous year. The report should include, but is not limited to the following:

- A description of how HRD funds were used.
- Training courses provided.
- Training courses attended.
- Educational resources purchased or leased.
- Educational materials developed.
- Description of collaboration with partners, such has those serving high risk populations.
- Attendance at the 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 needs were identified and addressed, as well as barriers and opportunities identified in TB HRD.

Public Health Laboratory Strengthening:
The recipients' annual performance report for the Laboratory Strengthening Component should include:

- An organizational chart of personnel performing TB laboratory testing that includes names of staff in each position. Include a designated laboratory point of contact with contact information. Please indicate staff that are funded through TB Cooperative Agreement funding.
- A brief description of the testing methods used in the laboratory and/or access through referral, including those for specimen processing, direct detection, AFB smear, culture, ID, growth-based DST, molecular sequencing DST, WGS (for clinical and/or

surveillance purposes), genotyping, and IGRA as applicable and a brief overview of the overall laboratory testing algorithm. The narrative should include information on the flow of specimens in the laboratory, how testing is reflexed, referral practices, reporting protocols, electronic test ordering and reporting, number of days per week testing is performed, and if and how WGS data is sent for surveillance purposes. A visual laboratory testing algorithm should be included. Plans to implement new technologies (e.g., IGRA, molecular testing such as next generation sequencing) should be discussed here.

- Laboratory workload and TAT data (use Performance Progress and Monitoring Reports Forms A and D) for the previous calendar year (January-December) and year-to-date (January-June).
- **Laboratory Element 1:** Ensure availability of high-quality and timely core TB laboratory services.
- **Laboratory Element 2:** Promote continual advancement of laboratory efficiency and quality assurance using laboratory-specific data.
- **Laboratory Element 3:** Communicate and collaborate with partners (e.g., health care providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

Laboratory Workload and TAT Data

Workload Volume Data

Report the workload volume indicators listed below:

1. Total number of clinical specimens 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.
    1. Of these, report the number of individual patients for whom at least one culture was positive for *Mycobacterium Tuberculosis* complex (MTBC).
    2. Of these individuals positive for MTBC by culture, report the number initially positive by NAAT from a clinical specimen in your laboratory. Note: This number should not include specimens or processed sediments referred for NAAT only.

3. Number of individual patients for whom a clinical specimen was tested directly with a NAAT.

    (This includes testing performed in-house and referred testing.)

    a. Of these, report the number of individual patients for whom a NAAT result was positive for MTBC. For laboratories that accept referred specimens or sediments for NAAT-only, this number may be higher than data reported for 2b above.

4. 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.

5. Number of individual patients for whom first-line MTBC DST was performed and/or, if DST was not performed in-house, for whom an isolate was referred to another laboratory for DST.
6. If applicable, number of individual patients for whom in-house molecular sequencing DST was performed. Molecular sequencing DST method(s) should be described in the narrative section. Note: Probe-based methods such as Xpert MTB/RIF and line probe assays should not be included.
    1. Number of individual patients for whom in-house molecular sequencing DST was performed for clinical specimens/sediments.
    b. Number of individual patients for whom in-house molecular sequencing DST was performed for MTB isolates.
7. Number of individual patients for whom the laboratory either referred an isolate of MTBC to another laboratory for genotyping or provided CDC with FASTQ files from in-house WGS for genotyping analysis.
8. If applicable, provide the total number of IGRAs performed in-house.

Turnaround Time (TAT) Data

Report the calculated TAT for each recommendation as described below. Calculations should be in **calendar days**. Current performance targets and instructions on how to calculate TATs can be found at *https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Cooperative-Agreement-Toolkit.aspx*.

1. 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.
2. Use fluorescent acid-fast staining and promptly transmit results. Benchmark is report within 1 day from specimen receipt. Report cumulative percent transmitted within 1, 2, and 3 calendar days.
3. Promote use of NAAT. Report the percent of patients tested by NAAT that had a positive result reported within 48 hours of specimen receipt.
4. Use rapid methods to identify and report isolates as MTBC as soon as possible. Benchmark is report within 21 days from specimen receipt. Report percent of MTBC isolates identified from initial diagnostic specimens within 21 calendar days of receipt.
5. Determine growth-based susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report result promptly. Report percent of rifampin results reported for initial diagnostic specimens within 17 days of MTBC identification from culture. Isolates sent out for referral testing should be included and indicated in the comments. Do not include molecular testing data; if routinely performing molecular testing in lieu of growth-based DST, please indicate in the comments.
6. For laboratories that perform in-house molecular sequencing DST methods, report results within 11 days (testing of specimens or MTBC isolates). Report the mean and range TAT in days, by each method performed, for specimens and MTBC isolates, separately. For specimens, measure from date of receipt to result report. For MTBC isolates, measure from date of receipt (if a referred isolate) or date of ID (if ID is performed in-house) to result report. Note: Probe-based methods such as Xpert MTB/RIF and line probe assays should not be included.

7. For laboratories that perform in-house IGRA testing, results should be reported within 4 days of collection. Report the mean number of days between specimen collection and reporting of IGRA test result.

Laboratory Element 1: Ensure availability of high-quality and timely core TB laboratory services.

All laboratories should provide a work plan on laboratory activities related to improving each of the national benchmark TAT recommendations to include:

- Laboratory-specific numerical goals for each TAT indicator (specimen receipt, AFB smear, NAAT, ID, growth-based DST, molecular sequencing DST, and IGRA). Laboratory-specific goals should be chosen to strive to achieve or exceed national targets. If the laboratory is currently meeting national targets, maintaining the current TAT or a new measurable goal should be listed.
- Specific strategies and activities for achieving the state TAT goals.
- Progress and obstacles related to TAT for previously stated objectives
- Laboratory workload and TAT data (use Performance Progress and Monitoring Reports Forms A and D) for the previous calendar year (January-December) and year-to-date (January-June).

Laboratory Element 2: Laboratories, regardless of volume, should provide **at least two** measurable objectives and related strategies for Element 2.

To improve laboratory efficiency and quality assurance during the 5-year period of performance, laboratory-specific data should be monitored, frequently reviewed, and analyzed to explore opportunities for process improvements. Laboratories should strive for continual quality improvement (e.g., workload and turnaround numbers/percentages over time, testing algorithms, contamination rate, equipment improvements/challenges). Report on the following information:

- Measurable objectives to improve efficiency and quality assurance for your laboratory.
- Specific strategies and activities related to improvements.
- Progress, obstacles, and outcomes related to gained efficiencies to previously stated objectives.
- Target completion date/timeline and measure of success.

Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

Laboratory Element 3: Laboratories, regardless of volume, should provide **at least two** measurable objectives and related strategies for Element 3.

Laboratories will communicate and collaborate with partners (e.g., health care providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

Laboratories could initiate plans for increased communication or educational opportunities, provide evidence-based practices, partner on electronic ordering and reporting systems, and collaborate with TB Programs and clinical laboratories to improve awareness and understanding of laboratory services (e.g., development of specimen collection guidelines or promotion of available in-house or reference laboratory services).

Report on the following information:

- Measurable objectives to improve communication and collaboration with partners for your laboratory.
- Specific strategies and activities to improve communication and collaboration.
- Progress, obstacles, and outcomes related to previously stated objectives.
- Target completion date/timeline and measure of success.

Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

Carryover requests

Carryover requests should be submitted for applicable circumstances. Expanded Authority will allow routine carryover of unspent and unobligated funds from prior years when noted in block 12 of the FFR. An electronic FFR is available in GrantSolutions.

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

- Express a bona fide need for permission to use an un-obligated balance.
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.
- Include third party contributions and budget gaps.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

Recipients will meet this annual requirement to report on performance measures with the submission of an Annual Performance Report. **However, CDC will 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.

Recipients 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.

The ARPE report is due each year by March 31. The Final ARPE report is due for the current year minus two (for example, in 2025, the Final report is due for year 2023). The Preliminary

ARPE report is due for the current year minus one (for example, in 2025, the Preliminary report is due for year 2024). **The due dates for the Targeted Testing report for all program areas follows the same schedule as the Contact Investigation report.**

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 120 days after the end of the period of performance. The Final FFR is due 120 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the period of performance, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

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

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $30,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
"Commodity" means any material, article, supplies, goods, or equipment;
"Foreign government" includes any foreign government entity;
"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;
b. contact name with phone, fax, and e-mail;
c. agreement number(s) if reporting by agreement(s);
d. reporting period;
e. amount of foreign taxes assessed by each foreign government;
f. amount of any foreign taxes reimbursed by each foreign government;
g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
MARTHA

Last Name:
BOISSEAU
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Address:

Martha Boisseau, MPH, CHES

Deputy Chief, Field Services Branch

Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

1600 Clifton Road, NE.

MS: US H24-4

Atlanta, GA 30329-4027

Telephone: 770-488-6261

E-mail: mboisseau@cdc.gov

For **laboratory technical assistance**, contact:

Angela Starks, Ph.D.

Chief, Laboratory Branch

Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

1600 Clifton Road, NE

MS H24-4

Atlanta, GA 30329-4027

Telephone: 404-639-3205

E-mail: astarks@cdc.gov

Telephone:
770-488-6261

Email:
mboisseau@cdc.gov

Grants Staff Contact

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

First Name:
TERRIAN

Last Name:
DIXON

Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
Terrian Dixon, Grants Management Specialist / Officer

Centers for Disease Control and Prevention

Office of Financial Resources

Office of Grants Services

District Chamblee, Bldg. 2900 TCU-3

Atlanta, Georgia 30341

E-mail: tdixon@cdc.gov

Telephone:
Email:
tdixon@cdc.gov
For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

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

H. Other Information

Following is a list of acceptable application attachments that can be submitted using PDF, Word, or Excel file formats 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
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:
Letters of Support

Organization Charts

Memorandum of Understanding (MOU)

Other relevant supporting information may be attached and must be clearly labeled.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 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 NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see https://www.cdc.gov/grants/additional-requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

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 period of performance. Traditionally, budget periods are 12 months or 1 year.

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.

Community engagement: The process of working collaboratively with and through groups of people to improve the health of the community and its members. Community engagement often involves partnerships and coalitions that help mobilize resources and influence systems, improve relationships among partners, and serve as catalysts for changing policies, programs, and practices.

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

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

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: 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. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. https://www.cdc.gov/grants/additional-requirements/index.html.

Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment (from Executive Order 13985).

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

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 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 "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Health Inequities: Particular types of health disparities that stem from unfair and unjust systems, policies, and practices and limit access to the opportunities and resources needed to live the healthiest life possible.

Healthy People 2030: 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: The act of creating environments in which any individual or group can be and feel welcomed, respected, supported, and valued to fully participate. An inclusive and welcoming climate embraces differences and offers respect in words and actions for all people.

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.

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.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

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 non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

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.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

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 results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

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.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

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

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: The non-medical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. https://www.cdc.gov/about/sdoh/index.html

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.

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

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.

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

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is

free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

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

NOFO-specific Glossary and Acronyms

ARPE: Aggregate Report for Program Evaluation

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

COE: Centers of Excellence

DA: Direct Assistance

DST: Drug susceptibility test

EDN: Electronic Disease Notification

FA: Financial Assistance

IGRA: Interferon gamma release assay

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.

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

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

MDDR: Molecular Detection of Drug Resistance

MDR TB: Multidrug Resistant Tuberculosis

MTBC: *Mycobacterium tuberculosis* complex

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

NTCA: National Tuberculosis Coalition of America

National TB Indicators Project (NTIP): Monitoring system using standardized performance measures (i.e., indicators) to track progress toward national objectives.

Rapid Detection Test: Test for the detection of the presence of *M. tuberculosis* complex (MTBC) performed directly on a clinical specimen (e.g., NAAT).

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.

TAT: Turnaround time

TEDS: Tuberculosis Emergency Drug Stockpile

TST: Tuberculin Skin Test

WGS: Whole genome sequencing