Centers for Disease Control

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

Tuberculosis Elimination and Laboratory Cooperative Agreement
CDC-RFA-PS20-2001
Application Due Date: 09/05/2019

Tuberculosis Elimination and Laboratory Cooperative Agreement
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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS20-2001. 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 this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS20-2001

E. Assistance Listings (CFDA) Number:

93.116

F. Dates:

1. Due Date for Letter of Intent (LOI):	**N/A**
2. Due Date for Applications:	**09/05/2019**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Date for Informational Conference Call:

The TB Program information call will be conducted on **July 10, 2019, 2pm - 3pm ET**. The registration link is https://cc.readytalk.com/r/bw58kbpz89y9&;eom

The Public Health Laboratory information call will be conducted on **July 17, 2019, 3pm - 4pm ET**. The registration link is : https://cc.readytalk.com/r/87n9c9r85hu9&;eom

Note: participants for either call must register in advance of the call date in order to participate

G. Executive Summary:

1. Summary Paragraph:

CDC announces available Fiscal Year (FY) 2020 funds to continue complementing TB prevention and control and laboratory services and activities at state and local levels to reduce TB morbidity and mortality. Goals include preventing transmission of *M. tuberculosis* (TB) and preventing persons from progressing from latent TB infection to TB disease. Funding levels will

be determined by formulas reflecting TB disease incidence, case complexity, program performance, and laboratory workload data.

Strategies and activities include diagnosis/treatment of persons with TB disease; persons with LTBI; evaluation of immigrants/refugees with TB or LTBI; targeted testing and treatment of LTBI; program planning, evaluation, and improvement; epidemiologic surveillance and response; human resource development and partnership activities; and public health laboratory strengthening.

Expected outcomes include (not limited to): decreases in TB incidence; increases in patients completing treatment within 12 months; increases in TB cases with HIV and drug susceptibility testing results; increases in LTBI testing and treatment completion rates of those who are recommended for treatment; increases in accuracy and completeness of surveillance, genotyping, and whole-genome sequencing data; improvement in turnaround times for specimen receipt and laboratory testing; increases in programs implementing TB elimination plans; and increases in sharing of best practices within and between state/local programs.

a. Eligible Applicants:	Open Competition
b. NOFO Type:	Cooperative Agreement
c. Approximate Number of Awards:	61
d. Total Period of Performance Funding:	$0
e. Average One Year Award Amount:	$0
f. Total Period of Performance Length:	5
g. Estimated Award Date:	12/01/2019
h. Cost Sharing and / or Matching Requirements:	N

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

TB is an airborne disease and globally, a leading cause of death. One fourth of the world's population is infected with TB. In 2017, 10.0 million people around the world became sick with TB disease. There were 1.3 million TB-related deaths world-wide, and TB is the leading killer of people who are HIV infected. A total of 9,105 TB cases (a rate of 2.8 cases per 100,000 persons) were reported in the United States in 2017. This is a 1.6% decrease in the number of cases reported in 2016 and the lowest case count on record in the United States. While the United States continues to make slow progress, current strategies will not, alone, lead to TB elimination in this century. Meeting the U.S. TB elimination goal will require an added focus on testing and treating high-risk persons with latent TB infection (LTBI) to prevent them from developing active

TB disease. CDC estimates that up to 13.0 million people in the United States have LTBI and over 80% of U.S. TB cases result from longstanding, untreated LTBI. This NOFO supports the continued focus on identifying and curing persons with TB disease, but also includes the addition of a targeted testing and treatment strategy for LTBI.

TB disproportionately affects certain populations, including those who are non-U.S.-born, with human immunodeficiency virus (HIV) infection or diabetes, experiencing homelessness, who are incarcerated, and who use illicit substances. The TB incidence rate among non-U.S.-born persons in 2017 was approximately 15 times greater compared to U.S.-born persons, and the percentage of TB cases occurring in non-U.S.-born persons continues to increase, reaching 70.1% in 2017. Achieving TB elimination in the United States will require focusing on persons in these high-risk groups – an approach that is reinforced by this NOFO.

CDC is continuing a 30-year strategy of funding TB programs through cooperative agreements (CoAgs). The primary responsibility for developing and implementing TB Prevention and Control (P&C) and laboratory activities rests with state and local health departments, and this funding is intended to complement those efforts. The intent of this funding is not to supplant or reduce state and local investment in TB control activities and responsibilities (e.g., provision of medications, in-patient care, and health department facilities).

b. Statutory Authorities

This program is authorized under Section 317E(a) of the Public Health Service Act, [42 U.S.C. Section 247b-69(a)] as amended.

c. Healthy People 2030

This NOFO addresses the Healthy People 2020 Immunization and Infectious Diseases topic area. For more information, visit: https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives?topicId=23.

d. Other National Public Health Priorities and Strategies

This NOFO relates to the following national strategies.

- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Strategic Plan - https://www.cdc.gov/nchhstp/strategicpriorities/
- National Action Plan for Combating Multidrug-Resistant Tuberculosis - https://www.usaid.gov/what-we-do/global-health/tuberculosis/resources/news-and-updates/national-action-plan-combating-mdr
- U.S. National Strategy for Combating Antibiotic-Resistant Bacteria - https://www.cdc.gov/drugresistance/us-activities/national-strategy.html
- National Stakeholder Strategy for Achieving Health Equity - https://minorityhealth.hhs.gov/npa/templates/content.aspx?lvl=1&;lvlid=33&;ID=286

e. Relevant Work

This NOFO builds on the accomplishments realized through past CDC TB Prevention and Control (P&C) and laboratory strengthening Cooperative Agreements (CoAgs), which were in large part responsible for the reversal of the 1985–1992 resurgence of TB in the United States.

The resurgence was fueled by budget cuts, growing incidence of HIV infection, and the transmission of multidrug-resistant TB (MDR TB) in hospitals and other settings. Collectively, current and previous CDC TB CoAgs have helped ensure the downward U.S. TB incidence trends experienced over the past 20 years.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

The goal of this NOFO is to reduce morbidity and mortality caused by TB by:

- Preventing transmission of *M. tuberculosis* from persons with infectious disease to uninfected persons,
- Preventing persons from progressing from latent TB infection (LTBI) to TB disease, and
- Strengthening laboratory capacity to ensure that timely and reliable TB laboratory services are available.

Strategies and Activities	**Short-Term Outcomes**	**Intermediate**	**Long-Term**
Diagnosis/treatment of persons with TB disease · Advise providers on TB diagnosis and treatment · Manage cases and ensure treatment adherence	· Earlier patient diagnoses · **Increase in cases with HIV and drug susceptibility testing results** · **Increase in patients on/responding to appropriate treatment** · Shorter patient infectious periods	· Decrease of acquired drug resistance · **Increase in patients completing treatment within 12 months** · Decrease in TB recurrence	· **Decrease in overall TB incidence** · Decrease in TB morbidity and mortality · **Increase in programs implementing TB Elimination Plans** · Decrease in TB incidence among high-risk populations · Increase in
· Promote infection control	· Decrease in TB transmission	· Decrease in LTBI prevalence	
Diagnosis/treatment of persons with latent TB infection (LTBI) · Conduct contact investigations for infectious TB cases	· **Increase in contacts elicited/examined** · **Increase in treatment initiation for patients with LTBI who are recommended for treatment**	· **Increase in LTBI treatment completion rates** · Decrease in patients who progress from infection to disease	
· Examine immigrants/refugees with Class B notification	· **Increase in treatment initiation for patients with LTBI/prior pulmonary TB who are recommended for treatment**		

· Test and treat high-risk, targeted populations	· Increase in LTBI diagnoses and high-risk patients who initiate treatment		health equity among high-risk populations · Increase in ability to maintain program capacity and momentum toward TB elimination in an era of declining incidence and resources · Increase in availability of well-trained and informed public health practitioners, laboratorians, and health providers with knowledge and experience to accurately diagnose, treat, and prevent TB
<u>Program planning, evaluation, and improvement</u> · Conduct program evaluation to improve performance towards national/other performance measures	· Increase in program evaluation activities based on performance measures · Increase in implementation of remediation strategies · **Increase in identification/dissemination of best practices within and between state/local programs**	· Increase in adoption of best practices · Increase in programs meeting national performance targets · Increase in use of findings to inform policy changes	
<u>Surveillance</u> · Report cases in timely, accurate, and complete manner, including linkage of genotyping and whole-genome sequencing results	· **Increase in national accuracy and completeness of surveillance, genotyping, and whole-genome sequencing data** · **Increase in cases genotyped and linked to surveillance data**	· Increase in capability for cluster/outbreak detection · Increase in capacity to investigate/interrupt recent TB transmission · Increase in ability to inform TB elimination activities through epidemiologic analyses of surveillance data	
· Routinely review/prioritize investigation of TB clusters	· Increase in availability of better data to inform cluster investigations/targeted efforts to reduce cluster- and outbreak-associated transmission		
· Promote standardized collection/reporting of individual level LTBI data and develop LTBI surveillance plan	· Increase in local programs collecting core LTBI data on individual level · Increase in local programs with LTBI baselines/capacity to track treatment		
<u>Human resource development (HRD) and partnerships</u> · Develop and implement HRD plans	· Increase in availability/accessibility of competency-based education/training · Increase in awareness/use of HRD resources	· Increase in capacity to diagnose/treat high-risk populations in culturally sensitive manner · Increase in adoption of new technologies for TB and LTBI treatment	
· Collaborate with organizations and providers serving high-	· Increase in levels of TB awareness/knowledge among patients, providers, and		

risk populations	communities	(e.g. eDOT)	
Laboratory strengthening · Evaluate laboratory data/practices to address needed improvements · Ensure availability of high quality prompt core TB laboratory services	· **Decrease in turnaround times for specimen receipt, acid-fast bacillus smear, nucleic acid amplification, identification of MTBC, and growth-based or molecular drug susceptibility testing**	· Increase in efficiency, based on implementation of evidence-based policies and procedures and enriched collaborations	

i. Purpose

The purpose of this NOFO is to assist the current efforts of state, local, and territorial TB programs to prevent, control, and eventually eliminate TB in the United States. Funds will augment state/local investments in TB prevention and control activities; development of human resources through improved training, education, communications, and information dissemination; and strengthen laboratory capacity to ensure that timely and reliable TB laboratory services are available to health care providers and TB controllers.

ii. Outcomes

By the end of this 5-year project period, NOFO recipients must address all of the short-term, intermediate, and long-term outcomes in the logic model, as well as achieve all of the outcomes highlighted in bold-type in the logic model. 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 *https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Cooperative-Agreement-Toolkit.aspx*

iii. Strategies and Activities

Each TB program funded under this NOFO will be categorized according to one of the following definitions:

- **High-incidence jurisdiction:** Program reporting ≥150 TB cases annually, or
- **Low-incidence jurisdiction:** Program reporting < 150 TB cases annually.

Strategy 1: Diagnosis/treatment of persons with TB disease *(required for both high and low incidence jurisdictions)*

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

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

- Assess adequacy and appropriateness of therapy for each patient by reviewing initial regimen, susceptibility results, adherence, and response to therapy. Therapy should be consistent with American Thoracic Society/ Infectious Disease Society of America/Centers for Disease Control and Prevention guidelines. Refer to the following web link for more information: http://www.cdc.gov/tb/topic/treatment/default.htm.
- Seek expert consultation for treatment of MDR TB and other complex cases from 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.
- 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:

  http://www.cdc.gov/tb/topic/laboratory/default.htm

  http://www.cdc.gov/tb/topic/laboratory/rapidmoleculartesting/default.htm

  https://www.cdc.gov/tb/education/tb_coe/default.htm

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

- Collaborate with HIV/AIDS 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.
- Utilize, promote, and promulgate effective binational referral mechanisms for patients who may receive care along the U.S.-Mexico border or who may cross the border while taking treatment for TB. For more information, please see these links:

  http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb/

  http://www.migrantclinician.org/services/network/tbnet.html

- Partner with CDC Division of Global Migration and Quarantine (DGMQ) to support international and binational TB quarantine efforts.
- Establish a process to review case management activities routinely to ensure optimal patient care.
- Formulate and implement a plan for the elimination and interruption of transmission of *M. tuberculosis*, to be submitted to CDC by the end of year 1. This plan should be developed and implemented with ongoing collaboration with a TB elimination advisory committee.

Strategy 2: Diagnosis/treatment of persons with latent TB infection (LTBI)

Strategy 2a: Conduct contact investigations for infectious TB cases *(required for both high and low incidence jurisdictions)*

To accomplish the priority activity of eliciting contacts who are exposed to infectious TB and ensure that they are examined for TB or LTBI, the following should be conducted:

- Ensure that contact investigation activities are initiated and completed promptly; including interviewing TB cases or utilizing location-based methods to identify contacts, and ensuring that infected contacts begin and complete an appropriate diagnostic evaluation to exclude TB disease and a course of treatment for LTBI if recommended after TB disease has been excluded. Refer to the following web link for more information on treatment recommendations for LTBI: https://www.cdc.gov/tb/publications/ltbi/treatment.htm
- Assess reasons for cases with fewer than 3 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 2b: Examination of immigrants and refugees with TB or LTBI *(required for both high and low incidence jurisdictions)*

This strategy involves completing/reporting domestic TB follow-up examination of immigrants and refugees, and ensuring completion of TB and LTBI treatment if recommended. The following should be conducted:

- Ensure that immigrants and refugees classified as A, B1, or B2 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: http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6207a1.htm\

Strategy 2c: Targeted testing and treatment of LTBI in high-risk populations *(required for high incidence jurisdictions; strongly encouraged for low incidence jurisdictions)*

- Ensure that effective interventions are implemented to identify non-U.S.–born and locally-determined high-risk populations 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:
https://www.cdc.gov/tb/publications/ltbi/treatment.htm

- 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:

  http://www.idf.org/diabetesatlas/5e/diabetes-and-tuberculosis

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

- Partner with primary care providers serving high-risk populations to expand LTBI testing and treatment
- Report targeted testing and treatment data using the Aggregate Reports for Tuberculosis Program Evaluation (ARPE): Targeted Testing and Treatment of Patients with Latent TB Infection form

High incidence programs must:

1. Identify a process to choose local high-risk population(s) that is more site-specific than the general requirements of Strategies 2a and 2b. Establish a baseline for testing individuals identified as high-risk of having LTBI and/or progressing to TB disease*, within the first year of the CoAg, and identify a goal and strategy for scaling-up targeted testing for LTBI.
2. Establish a baseline for initiating and completing treatment for individuals diagnosed with LTBI who are recommended for treatment within the first year of the CoAg and identify a goal and strategy for increasing LTBI treatment initiation and completion rates.

*Populations at high 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.

Low incidence programs are **encouraged** to implement or maintain targeted testing and treatment activities in populations at high risk for LTBI and/or progression to TB disease, and to report outcomes as described above.

Strategy 3: Program planning, evaluation, and improvement *(required for both high and low incidence jurisdictions)*

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 PEN\TB ETN (Education and Training Network) biennial conference. TB CoAg funds can be used to support travel for the appointed TB program evaluation network focal point to attend the TB PEN\TB ETN conference.

Strategy 4: Epidemiologic Surveillance and Response*(required for both high and low incidence jurisdictions)*

To accomplish the priority tasks of 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 suspected TB by establishing collaborative relationships with appropriate reporting sources including:**
    - Hospitals and clinics (e.g., TB and HIV/AIDS and STD clinics).
    - Laboratories performing testing for mycobacteria.
    - Healthcare providers (e.g., pulmonary and infectious disease subspecialists).
    - Correctional facilities.
    - Homeless shelters.
    - Community and migrant health centers.
    - Pharmacies.
    - Other public and private facilities providing care to populations at risk for TB.
- **Ensure complete, accurate, and timely reporting of persons with confirmed or suspected TB by:**
    - Maintaining TB disease as a mandatory reportable condition as required by state and local laws.
    - Enhancing awareness among healthcare providers of the requirement to report TB cases.
    - Maintaining a passive surveillance data collection system that includes at least the data elements contained in the CDC Report of Verified Case of TB (RVCT).
    - Conducting active surveillance for TB when warranted because of a known or suspected TB 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: http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf
    - Creating/updating and submitting to CDC at least annually a TB surveillance quality assurance protocol as described in the CDC Quality Assurance for TB Surveillance Data Guide and Toolkit: ftp://ftp.cdc.gov/pub/Software/TIMS/2009%20RVCT%20Documentation/RVCT%20Training%20Materials/Quality%20Assurance%20Materials/.
- **Notify 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 Electronic Disease Surveillance System (NEDSS) standards.
    - Reporting to CDC complete and accurate data on all TB cases (regardless of whether the cases are considered "countable" in official case counts) using the Report of Verified Case of Tuberculosis (RVCT). (All RVCT data elements should be filled out completely according to CDC instructions for the RVCT: http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf).
    - Transmitting TB case notification messages via the National Notifiable Disease Surveillance System (NNDSS) or other CDC-approved system for all verified TB cases to CDC in a timely manner (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 prompt identification and investigation of TB genotype clusters by:**
    - Submitting at least one isolate from persons with culture-positive TB to a CDC-designated laboratory for genotyping in a timely manner.
    - 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 according to best practices for TB genotyping: http:// www.cdc.gov/tb/publications/factsheets/statistics/Genotyping_BestPractices.pdf
    - Promptly reviewing (within 1 week of receiving notification) and collaborating with CDC to investigate TB genotype cluster alerts generated by TB GIMS to determine whether a TB outbreak is occurring.
- **Ensure appropriate response to large TB outbreaks (≥10 cases diagnosed in a 3-year period that are related by recent transmission) by:**
    - Conducting timely and appropriate epidemiologic investigation of, and response to, TB outbreaks.
    - Reporting outbreak investigation and response activities to CDC at least monthly, including epidemiologic data and ongoing or planned interventions to control transmission (e.g., line lists of outbreak-related cases, epidemiologic links identified among patients, and results of contact investigations, including TB and

LTBI treatment outcomes).

- **If feasible**, 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 CDC LTBI case reporting form and protocol 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 the CDC RVCT.
    - Collecting data on all persons diagnosed with LTBI in public health department clinics consistent with data elements contained in the CDC RVCT.
    - Transmitting LTBI case notification messages via NEDSS or other CDC-approved system for all verified LTBI cases to CDC in a timely manner (within 1 week for newly verified cases and within 1 month for previously verified cases with updated information).

Strategy 5: Human Resource Development (HRD) and Partnerships *(required for both high and low incidence jurisdictions)*

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. This strategy involves developing and implementing HRD activities and collaborating with organizations and providers serving high-risk populations. As part of this strategy, recipients are expected to:

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

Strategy 6: Public Health Laboratory Strengthening

This strategy ensures the availability of high quality and prompt core laboratory services for TB and the ability to evaluate local laboratory data and practices to identify and address areas for improvement. This is accomplished by public health laboratories through the following:

- Ensuring availability of reliable, timely laboratory services and use of recommended 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 (e.g., refer to Clinical and Laboratory Standards Institute (CLSI) *Susceptibility Testing of Mycobacteria*, Nocardia *spp., and Other Aerobic Actinomycetes.* 3rd ed. CLSI standard M24).
- Developing, implementing, monitoring, and reporting on strategies and activities to meet CDC recommended turn-around times (TATs) by establishing internal laboratory-specific goals, strategies/activities to improve TATs for specimen receipt, acid-fast bacillus (AFB) smear, nucleic acid amplification, identification of MTBC, and drug susceptibility testing (DST).
- Ensuring that testing methods and algorithms selected are the most efficient and eliminate redundancies for workload volume of specimens received and laboratory capacity. Programs exist to assist with higher-level review of current laboratory workflows.
- Processing fewer than 20 specimens per week (the recommended minimum level of activity to maintain proficiency) in a laboratory should prompt consideration of collaboration with another laboratory. Performing first-line DST for <50 patient isolates per year should prompt consideration of referral of isolates to the National DST Reference Center or another laboratory (https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Self-Assessment-Tool.aspx).
- Continuing to provide access to nucleic acid amplification testing (NAAT) for detection of MTBC directly from clinical specimens.
- Ensuring *rpoB* mutations detected by Xpert MTB/RIF (or other probe-based methods, as applicable) are confirmed by DNA sequencing.
- Ensuring information about reference services including testing algorithms of CDC'S Molecular Detection of Drug Resistance (MDDR) Service and the National DST Reference Center are in place for rapid reflex when applicable.
- Ensuring that at least one isolate from all persons with culture-confirmed TB is submitted for genotyping in a timely manner.
- Supporting as applicable, dependent on patient population, the use of interferon gamma release assays (IGRA) in mutual agreement with the TB Program to aid in diagnosing tuberculosis disease and latent tuberculosis infection.
- Monitoring and assessing local data (i.e. 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 as become available to improve test results, turnaround times, efficiency of test methods and staff, and patient management.
- 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 programs and CDC-funded organizations:

Applicants should develop a plan and timeline for working with other relevant CDC-funded programs in their jurisdiction that are targeting the same populations. Other partners that TB programs should collaborate with include those funded by 1) the Division of Viral Hepatitis, 2) the Division of Sexually Transmitted Diseases Prevention, 3) the Division of HIV/AIDS Prevention, 4) the Division of Diabetes Translation, 5) Division of Global Migration and Quarantine, and 6) the Immunization Services Division. The expectation of the collaboration is to improve technical and program guidance, strategies and relevant activities, and program evaluation efforts.

Collaborations should also exist between states and the CDC-funded TB Centers of Excellence for Training, Education, and Medical Consultation: https://www.cdc.gov/tb/education/tb_coe/default.htm. 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.

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;
- medical and nursing schools and related teaching hospitals, public health schools and associations;
- regional TB controller associations;
- TB advisory councils;
- U.S. panel physicians and civil surgeons (as guided by CDC);
- STD/HIV Prevention and Training Centers;
- Viral Hepatitis Education and Training Centers;
- Health Resources and Services Administration (HRSA) primary care centers;
- AIDS Education and Training Centers;
- Substance Abuse and Mental Health Services Administration (SAMSHA);
- Addiction Technology Transfer Centers;
- Refugee Resettlement Assistance Agencies
- 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 (i.e., correctional facilities, including federal bureau of prisons and immigrations and customs facilities; homeless shelters, etc.)
- Each recipient will collaborate with HIV/AIDS 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: http://www.cdc.gov/nchhstp/preventionthroughhealthcare/docs/PreventionthroughHealthCare-010512.pdf
- 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:

  https://www.ice.gov/detention-standards/2011

  https://www.cdc.gov/tb/programs/laws/menu/default.htm

- Recipients are encouraged to communicate with Health Care for the Homeless Council as potential partners to address TB control among the homeless: http://www.nhchc.org/resources/clinical/diseases-and-conditions/tuberculosis/
- Recipients are encouraged to collaborate on trainings with HIV/AIDS, STD, and viral hepatitis training partners and to integrate disease content as appropriate in courses as outlined by the NCHHSTP's Program Collaboration and Service Integration (PCSI) Strategy. Go to the following link for more information: https://www.cdc.gov/nchhstp/programintegration/Default.htm
- 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 www.hrsa.gov/opa/.
- Recipients are encouraged to collaborate with other laboratory professionals (state, local, clinical, commercial) and laboratory organizations (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 managers' course (local public health staff should attend a COE Fundamentals of TB Control Programs Course).

2. Target Populations

Targeted efforts to diagnose and complete treatment of TB in populations at high 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 high 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
- Persons living with HIV and others who are immunosuppressed.
- Persons with diabetes with additional risks for TB.
- 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, or other vulnerable people in the target population who 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

(https://www.cdc.gov/tb/education/tb_coe/default.htm) and the following websites:

https://www.cdc.gov/tb/topic/populations/HealthDisparities/default.htm , Find TB Resources

https://findtbresources.cdc.gov/, and Racial and Ethnic Approaches to Community Health (REACH)

https://www.cdc.gov/nccdphp/dnpao/state-local-programs/reach/.

a. Health Disparities

Health disparities are a particular type of health difference closely linked with social or economic disadvantage based on characteristics historically linked to discrimination or exclusion. CDC is committed to improving the health of people disproportionately affected by TB. Programs should use data to identify communities within their jurisdictions disproportionately affected by TB and related diseases and conditions, and plan activities to help eliminate health disparities. To achieve TB elimination, ongoing efforts must address the persistent disparities that exist. 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.

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. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.

iv. Funding Strategy

CDC will use a funding formula for all three components of the 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, 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 p. 39 of this document under 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 Objective,
- information included in annual performance report

Standardized performance measures established in the National TB Indicators Project (NTIP)

https://www.cdc.gov/tb/programs/evaluation/pdf/ntipuserguide.pdf 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.

CDC will monitor recipients performance by assessing progress towards reaching National Tuberculosis Laboratory Performance Targets for specimen receipt, AFB smear, identification, drug susceptibility testing, and nucleic acid amplification. 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. Site visits and the Tuberculosis Laboratory Aggregate Report will be used as opportunities to encourage program evaluation using 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.
- 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)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. 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/additionalrequirements/ar-25.html.

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 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

Performance measures for National TB Program Objectives are outlined under the National TB Indicators Project (NTIP).

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

The Program Evaluation Plan should describe the process the applicant/recipient will use to increase their understanding of factors contributing to their performance. If the applicant/recipient 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 award year. In all cases, CDC reserves the right to assign program evaluation topics that advance the goal of national TB elimination.

Applicants/recipients 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 should submit a program evaluation plan for the first year that includes the following information:

i. Background for program evaluation focus area:

    1. 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)

    2. Describe how the applicant intends to use findings and the expected impact on the program

ii. Program Evaluation Plan

    1. Define the evaluation objectives and\or key evaluation questions. Each objective should be Specific, Measurable, Achievable, Realistic and Time-bound (SMART)

    2. For each program evaluation objective, describe the methods and timelines for data collection and analyses

Each applicant\recipient 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.

Cohort Review Plan
Each applicant should describe plans 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. Additional information on conducting cohort reviews is also published in the CDC document, "Understanding the TB Cohort Review Process: Instruction Guide" accessible online at *http://www.cdc.gov/tb/education/cohort.htm*.

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 prompt core laboratory services for TB.

All laboratories, regardless of volume, should provide laboratory activities related to improving each of the national TB laboratory TAT performance targets to include:

- Laboratory-specific measurable goals for improving each TAT (specimen receipt, AFB smear, ID, DST, and NAAT). 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.
- Updates from subsequent annual performance reports should describe progress made towards achieving previously stated goals
- Description of specific strategies and activities for achieving the stated goals
- Explanation of potential obstacles to meeting the stated goals
- In tabular form, report the laboratory's data for workload and TAT indicators for the previous calendar year and year-to-date (January–June). 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*

Volume Considerations for Addressing Laboratory Elements 2 and 3

Laboratories receiving ≤ 1,000 clinical specimens each year should provide at least one measureable outcome for both Elements 2 and 3 as described below. Those laboratories receiving 1,001–5,000 clinical specimens each year should provide at least two measurable objectives, and those receiving ≥ 5,001 clinical specimens each year should provide at least three measurable objectives for Elements 2 and 3.

Laboratory Element 2:

Laboratories will implement process improvements during the 5-year project period and report on gained efficiencies from these changes in practice.

To improve laboratory efficiency and quality assurance, local data (i.e., laboratory-specific data) should be monitored, frequently reviewed, and analyzed to explore opportunities for process improvements specific to laboratory testing volume and services for continual quality improvement (e.g., contamination rate, workload and turnaround numbers/percentages over time,

testing algorithms, equipment improvements/challenges). Report on the following information below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities related to improvements should be described.
- Progress, obstacles, and outcomes related to gained-efficiencies to previously stated objectives should be updated in subsequent annual performance reports.
- 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 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 should initiate plans for increased communication or educational opportunities for specimen collection and submission with TB Programs and other laboratories, find opportunities to apply evidence-based local practices within the broader public health system, and collaborate with TB Programs and local hospitals 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 below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities to improve communication and collaboration should be described.
- Progress, obstacles, and outcomes related to previously stated objectives should be updated in subsequent annual performance reports.
- Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants (see Eligibility Section) must have the organizational capacity to develop, implement, and manage the work necessary for a TB control program and TB laboratory and demonstrate ability to execute the strategies and activities, and meet stated outcomes successfully. 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;

- demonstrate briefly the capacity to manage persons who have suspected or active TB, including provision of clinical care with appropriate medications, medical consultative services, and infection control and coordination with other health-care 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
- provide an organizational chart of personnel performing TB laboratory testing including names of staff in each position
- provide a brief description of the test methods used in the laboratory, including those for specimen processing, direct detection, AFB smear, culture, identification, DST, and interferon gamma release assay (IGRA) as well as a brief overview of the overall laboratory testing algorithm. A visual testing algorithm may also be included.
- identify designated focal points for education and training, program evaluation, and laboratory, including their contact information

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, as long as 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, in order to achieve the outcomes for the following strategies:

- Diagnosis/treatment of persons with TB disease
- Diagnosis/treatment of persons with latent TB infection (LTBI)
- Program planning, evaluation, and improvement
- Surveillance
- Human resource development (HRD) and partnerships
- Public health 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: https://www.cdc.gov/tb/education/funding-opportunity-notice.htm

Public Health Laboratory Strengthening

Public health laboratory work plans should include an organizational chart with staff members, a designated point of contact, description of testing methods and algorithm, and 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 prompt core laboratory services for TB.
- **Laboratory Element 2:** Promote continual advancement of laboratory efficiency and quality assurance through the use of local data (i.e., your laboratory-specific data).
- **Laboratory Element 3:** Collaborate with partners (e.g., healthcare providers, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

To view an example of a public health laboratory work plan, please visit the TB NOFO Resource webpage at: https://www.cdc.gov/tb/education/funding-opportunity-notice.htm

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:

- Providing assistance to 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 in regards to timely and reliable laboratory testing and reporting of laboratory data.
- Conducting conference calls with TB program, laboratory staff and CDC project officers as well as other relevant project personnel as needed to assist in successful implementation of proposed activities.
- Encouraging participation in webinars and awardee 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 time line (e.g., 30 days).

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

Prevention and Control (P&C)

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

- Providing assistance 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 programmatic consultation and technical assistance in the development and implementation of new diagnostics and treatment services pertaining to TB control and prevention and to expand the reach of the population served.
- 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 project period.

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:	Cooperative Agreement CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.
2. Award Mechanism:	93.116

NU52PS - PS20-2001 NU52 Cooperative Agreement for Tuberculosis Control

3. Fiscal Year:	2020
4. Approximate Total Fiscal Year Funding:	$0

5. Approximate Period of Performance Funding: $0

This amount is subject to the availability of funds.

Estimated Total Funding: $0
6. Approximate Period of Performance Length: 5 year(s)
7. Expected Number of Awards: 61

8. Approximate Average Award: $0 Per Budget Period

9. Award Ceiling: $0 Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor: $0 Per Budget Period

11. Estimated Award Date: 12/01/2019
12. Budget Period Length: 12 month(s)

Throughout the project period, 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 (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total 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.
Applicants may request federal personnel, equipment, medication from the national TB stockpile, or supplies as Direct Assistance (DA), in lieu of a portion of their Financial Assistance (FA). To address staffing and/or program expertise deficits, applicants may convert FA to DA to recruit staff with the requisite training, experience, and expertise (e.g. Public Health Associate Program [PHAP] staff). Refer to: https://www.cdc.gov/stltpublichealth/grantsfunding/direct_assistance.html for information on DA for assigning CDC staff to State, Tribal, Local, and territorial Health Agencies.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Others (see text field entitled "Additional Information on Eligibility" for

clarification)

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)
Local governments or their bona fide agents
Territorial governments or their bona fide agents in 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.

2. Additional Information on Eligibility

Competition is limited to 61 project areas, including 50 state public health agencies or their bona fide agents; the cities of Los Angeles, CA; San Francisco, CA; San Diego, CA; Houston, TX; Chicago, IL; New York, NY; Philadelphia, PA; Baltimore, MD; Washington, D.C.; and the territorial governments of Puerto Rico and U.S. Virgin Islands. Eligible applicants with laboratories can apply for laboratory funding.

In accordance with the statutory authority provided in Section 317E(a) of the PHS Act (42 USC 247b-6(a)) that limits HHS/CDC's authority to funding states, political subdivisions, and other government entities to conduct TB preventive health service programs; and HHS/CDC's discretionary authority to further limit eligibility for programmatic reasons, eligibility for CDC RFA-PS20-2001 is limited to the 61 official state, territorial, and city/district jurisdictions that are current recipients of Prevention and Control federal funds under CDC-RFA-PS15-1501, the Tuberculosis Elimination and Laboratory Cooperative Agreement. Eligible applicants include 50 states, eight (8) major U.S. cities (Baltimore, Chicago, Houston, Los Angeles, New York City, Philadelphia, San Diego, and San Francisco), the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. Eligible applicants with laboratories can apply for laboratory funding.

In order to provide a coordinated and complete public health approach to TB prevention and control, applicants must already have in place (via historical CDC funding and collaboration) the necessary public health infrastructure and possess the experience needed to carry out the required programmatic functions successfully. This includes having authority to: conduct disease surveillance; report surveillance data to CDC; respond to outbreaks; contain emerging disease threats; and conduct disease investigation, intervention, and follow-up.

Eligibility is also limited to the aforementioned 61 jurisdictions based on the following reasons.

1. **Maintaining the TB control infrastructure**: As stated in the 2000 Institute of Medicine report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, it is of utmost importance to maintain the existing public health infrastructure for prevention, control, and elimination of TB, especially in an era of declining resources. Discontinuation of funds to currently/historically funded areas will result in deterioration of the TB control programs/capacity and elevate the risk of resurgence of TB, similar to the sharp rise in TB cases experienced in the United States during the 1980s and 1990s, after the discontinuation of categorical TB funding.
2. **Consistency of distribution of TB cooperative agreement funds**: Since fiscal year 2005, CDC has gradually redistributed cooperative agreement funds based on a data-driven formula, in order to align funding with changing TB epidemiology. This formula has ensured that CDC's finite TB resources are distributed in a predictable/reliable manner, and that the federal investment in TB prevention and control is based on need and performance, as related to TB burden.

3. Justification for Less than Maximum Competition

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

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.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into

which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/SAM/.

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.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http://fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS	Same day but can take 8	Register early! Log into grants.gov and

		number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this 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 or postmarked by)

Due Date for Letter of Intent: **N/A**

b. Application Deadline

Due Date for Applications: **09/05/2019** , 11:59 p.m. U.S. Eastern Standard 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.

Date for Information Conference Call

The TB Program information call will be conducted on **July 10, 2019, 2pm - 3pm ET**. The

registration link is https://cc.readytalk.com/r/bw58kbpz89y9&;eom

The Public Health Laboratory information call will be conducted on **July 17, 2019, 3pm - 4pm ET**. The registration link is : https://cc.readytalk.com/r/87n9c9r85hu9&;eom

Note: participants for either call must register in advance of the call date in order to participate

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa)) /Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization

representative to include the original submission date, organization's EIN and DUNS.
When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

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

LOI is not requested or required as part of the application for this NOFO

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 file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)
A project abstract is included on the mandatory documents list and must be submitted

at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

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 project period, 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 project period.

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. Target Populations and Health Disparities
Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will 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 Target Populations and Health Disparities requirements as described in the CDC Project Description.

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/od/science/integrity/reducePublicBurden/.
- 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 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 public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the 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. 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; or support vital records improvement efforts, as approved by CDC.
Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect 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 is provided on the TB resources page on the CDC internet at https://www.cdc.gov/tb/education/fundingEstimator.htm 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 2020.

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 your 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 Fundamentals of TB Control Programs

Course). For staff conducting contact investigations, it is highly encouraged that those individuals attend a COE contact investigation interviewing skills course. Utilization of 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.

In addition, HRD funds can be used to support travel for the TB training and education focal point to attend the TB ETN/PEN conference. Using HRD funds to attend other conferences should be discussed in advance with your program consultant.

Public Health Laboratory Strengthening: Applicants should use their 2019 funding amounts plus a 20% increase to estimate the amount of funds to request for 2020.

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 performing first-line DST for < 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.

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 2 CFR 200 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. Intergovernmental Review

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372, which established a system for state and local intergovernmental review of proposed federal assistance applications. Applicants should inform their state single point of contact (SPOC) as early as possible that they are applying prospectively for federal assistance and request instructions on the state's process. The current SPOC list is available at: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

16. 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.

17. 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 lobbying 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.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

- Recipients may not use funds for in-patient clinical care; out-patient services are allowed (e.g., tuberculin skin testing, chest radiography, medical evaluation, treatment)
- Recipients may not use funds to supplant state or local health department funds
- Recipients may not use funds to purchase drugs for treatment
- Emphasis must be given to directing the majority of funds to core TB control front-line activities, such as TB case management, targeted testing and treatment of LTBI, completion of treatment, contact investigation, and outreach activities with strong emphasis on using conventional directly observed therapy (DOT), or eDOT
- 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

Restrictions for public health laboratories:

- Laboratories performing first-line DST for < 50 patient isolates/year should consider referral of isolates to a reference laboratory for testing such as the National PHL DST Reference Center. *https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/TB-DST.aspx*
- Laboratories reporting for < 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.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit 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/additionalrequirements/ar-25.html

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. All application attachments must be submitted using a PDF file format. 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 the Grants.gov Online User Guide.
https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t=
Get_Started%2FGet_Started. htm

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 (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

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

A review panel will evaluate complete, eligible applications in accordance with the criteria below.
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

Evaluate the extent to which the applicant conforms to the following:

- **Problem statement: (2 points)**
  Applicant adequately described the core information relative to the public health problem in order to understand how the application response to the NOFO will address the problem for the jurisdiction or population served.
- **Purpose**: **(3 points)**
  Applicant adequately described how the application will address the public health problem identified in the problem statement.
- **Collaboration**: **(2 points)**
  Applicant adequately described how they will collaborate with CDC funded programs in their jurisdiction as well as external organizations such as Medicaid programs, health plans, primary care settings, safety-net providers, not-for-profit clinics, correctional settings, homeless shelters, community-based organizations, tribal communities, academic experts, submitters 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 in order to reduce TB morbidity and mortality in their jurisdiction
    - P&C - Increased proportion of Completion of Treatment; Increased drug susceptibility result reporting (DST); Improved program ability to effectively and efficiently adopt available state-of-the art technologies (diagnostics & treatment), and improved use of local data for greater effectiveness and transparency.
    - HRD - Improved ability of TB program staff to translate knowledge and skills

into practice.
    - Laboratory - Improvements in TATs, advancement in efficiencies based on implementation of evidence-based policies and procedures, and enrichment of collaborations. Prepared and informed TB public health staff and other partners regarding recommended practices for TB diagnosis and treatment.

- **Strategies and Activities**: **(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 how laboratory would ensure improvements in TATs, advancement in efficiencies based on implementation of evidence-based policies and procedures, and enrichment of collaborations. The laboratory activities described in the application include all those listed in the NOFO.

- **Workplans for 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.

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

- **Work Plan for Public Health Laboratory Strengthening: (10 points)**

The Work Plan must address the following:

- Identify laboratory point of contact
- Provide an organizational chart with personnel listed
- Provide a brief description of laboratory methods, workflow, and testing algorithms
- List strategies and activities for meeting defined objectives for each Laboratory Element that are appropriate to the laboratory level of service and workload
    - **Element 1:** Ensuring availability of high-quality and prompt core laboratory services for TB.
    - **Element 2:** Promoting continual advancement of laboratory efficiency and quality assurance through the use of local data (i.e., laboratory-specific data).
    - **Element 3:** Collaborating with partners (e.g., healthcare providers, TB Nurses, TB Programs, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

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 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:

- Describe how the program is organized, the nature and scope of its work and/or the capabilities it possesses **(5 points)**
- Describe experience and success in conducting TB prevention and control activities, including development and successful implementation of PE plan and especially aimed at targeted populations **(5 points)**
- Provide laboratory organizational chart with designated laboratory contact and laboratory testing methods and algorithm **(5 points)**
- Describe how applicant will assess staff competencies and develop a plan to address gaps through organizational and individual training and development opportunities. **(5points)**
- Demonstrates experience and capacity to coordinate with tribal governments and/or tribally designated organizations in their jurisdiction, if applicable **(5 points)**

Budget

CDC project officers will evaluate the extent to which the budget aligns with the proposed work plan and the anticipated awarded amount under the TB funding formula.

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 technical reviews of applications and provide feedback to all applicants. All eligible and technically acceptable applications submitted in response to this NOFO will be funded.

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 (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) 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 framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.
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.
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, 2019.

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 the DUNS, 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 or by U.S. mail.

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.
Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.
The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

- 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

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. 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.

Report	**When?**	**Required?**
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

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 target 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 publically 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 than120 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 45-page limit of the APR, recipients should use a maximum of 30 pages for P&C; 5 pages for HRD; and 10 pages for Laboratory Strengthening to cover performance reporting and continuation funding application.

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

- In BP 2020, the APR will be due August 31 for the activities performed January 1, 2020 through June 30, 2020.
- For BPs 2021 - 2024, 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 the 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:

i. Results and Conclusions of the prior years' program evaluation activities

1. Describe status of implementation of the program evaluation plan, including rationale for plan revisions and barriers and facilitators to plan completion.
2. Report findings, including barriers, facilitators and lessons learned, related to reaching performance targets.
3. Discuss limitations that may have affected the evaluation's findings

ii. Remediation Plan based on the prior year's program evaluation activities:

1. Describe how findings and lessons learned will be applied to improve program performance

2. Identify plans to share findings and lessons learned to promote program improvement (i.e. presentations, reports, webinars, conferences, publications).

3. Outline a plan and time line to evaluate the effectiveness of the remediation

iii. Background for the coming years' program evaluation focus area:

1. 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.

2. Describe how the applicant intends to use findings and the expected impact on the program

iv. Program Evaluation Plan for the coming year

1. Define the evaluation objectives and\or key evaluation questions. Each objective should be Specific, Measurable, Achievable, Realistic and Time-bound (SMART).

2. For each program evaluation objective, describe the data sources, methods and time lines 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:
Email:

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

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

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 the area of TB HRD.

Public Health Laboratory Strengthening:

The recipients annual performance report for the Laboratory Component should include:

- An organizational chart of personnel performing TB laboratory testing including names of staff in each position. Include a designated laboratory point of contact with contact information.
- A brief description of the methods used in the laboratory and/or access through referral, including those for specimen processing, direct detection, AFB smear, culture, identification, DST, and IGRA as applicable as well as a brief overview of the overall laboratory testing algorithm. The concise description should include information on overall flow of specimens in the laboratory, how testing is reflexed, referral practices, reporting protocols, electronic test ordering and reporting, and number of days per week testing is performed. A visual testing algorithm may also be included. Plans to implement new technologies (e.g., IGRA, molecular testing) should be discussed here.
- **Laboratory Element 1:** Ensure availability of high-quality and prompt core laboratory services for TB.
- **Laboratory Element 2:** Promote continual advancement of laboratory efficiency and quality assurance through the use of local data (i.e., your laboratory-specific data).
- **Laboratory Element 3:** Collaborate with partners (e.g. health care providers, TB Programs, TB Nurses, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

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

All laboratories, regardless of volume, should provide a narrative on laboratory activities related to improving each of the national benchmark TAT recommendations to include:

- Laboratory-specific measurable goals for improving each TAT (specimen receipt, AFB smear, ID, DST, and NAAT). Laboratory-specific goals should be chosen to achieve or exceed national benchmarks. If the laboratory is currently meeting national targets, maintaining the current TAT or a new measurable goal should be listed.
- Updates in subsequent annual performance reports should describe progress made towards achieving previously stated goals
- Description of specific strategies and activities for achieving the stated goals.
- Explanation of potential obstacles to meeting the stated goals
- In tabular form, report the laboratory's data for each of the following workload and TAT indicators for the previous calendar year and year-to-date (January - June). These data should reflect testing for your jurisdiction only (i.e., not work performed for another state).

Turnaround Times

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*.

- Promote rapid delivery of specimens to the laboratory. Benchmark is receipt within 1 day of specimen collection. Report cumulative percent received within 1, 2, and 3 calendar days.
- Use fluorescent acid-fast staining and promptly transmit results. Benchmark is report within 1 day from receipt of specimen. Report cumulative percent transmitted within 1, 2, and 3 calendar days.
- Reduce the average time for a laboratory to confirm and report tuberculosis cases using NAAT. The goal is 2 days from receipt of clinical specimen for 77% of cases that are later culture confirmed. Report the percent of MTBC culture-confirmed patients with a positive NAAT or other direct detection method that was reported within 48 hours of specimen receipt.
- Use rapid methods to identify and report isolates as MTBC as soon as possible. Benchmark is report within 14-21 days from receipt of specimen. Report percent of MTBC isolates identified from initial diagnostic specimens within 21 calendar days.
- Determine the susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report results promptly. Report percent rifampin results reported for initial diagnostic specimens within 17 days of identification of MTBC from culture. Do not include molecular testing data.
- Consider using in-house molecular methods for the detection of mutations associated with drug resistance, as appropriate. Not every public health laboratory will have sufficient volume or capacity to perform this testing. Turnaround time benchmarks using molecular methods for susceptibility testing have not been determined. Data is requested from those performing in-house testing to establish a baseline for separate turnaround times for clinical specimens/sediments and isolates. Data from both probe-based and sequencing methodologies should be included. If more than one method is performed, stratify TAT by method. This indicator may have some redundancy with the NAAT indicator if the methodology used also detects MTBC.

Testing of Clinical Specimens

- For in-house molecular DST, report the mean and range TAT in days for clinical specimens/processed sediments from specimen receipt until final report. Please stratify TAT by each method used.

Testing of MTBC Isolates

- For in-house molecular DST, report the mean and range TAT in days for MTBC isolates from date of receipt (if a referred isolate) or date of ID (if ID is performed in-house) until final report. Please stratify TAT by each method used.

- If IGRA is performed in-house (within the PHL), report the mean number of days between specimen collection and test result for an IGRA result to be reported.

Workload 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.

a. Of these, report the number of individual patients for whom at least one culture was positive for MTBC.
b. 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.
c. Of those individuals positive for MTBC by culture who had a positive NAAT from the clinical specimen, report the number of individual patients for whom the laboratory report of MTBC was provided within 48 hours of clinical specimen receipt.

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.) Do not include data for rapid species identification tests performed on isolates (e.g., ACCUPROBE).

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

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 growth-based MTBC first-line 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 DST was performed. Molecular DST method(s) should be described in the narrative section.

a. Number of individual patients for whom in-house molecular DST was performed for clinical specimens/sediments.
b. Number of individual patients for whom in-house molecular DST was performed for MTB isolates.

7) Number of individual patients for whom the laboratory referred an isolate of MTBC for genotyping.

8) If applicable, provide the total number of IGRAs performed in-house.

Volume Considerations for Addressing Laboratory Elements 2 and 3

Laboratories receiving ≤ 1,000 clinical specimens each year should provide at least one measurable objective for both Elements 2 and 3 as described below. Those laboratories receiving 1,001 - 5,000 clinical specimens each year should provide at least two measurable

objectives, and those receiving ≤ 5,001 clinical specimens each year should provide at least three measurable objectives for Elements 2 and 3.

Laboratory Element 2:

Laboratories will implement process improvements during the 5-year project period and report on gained efficiencies from these changes in practice in Annual Performance Reports.

To improve laboratory efficiency and quality assurance, local data (i.e., your laboratory-specific data) should be monitored, frequently reviewed, and analyzed to explore opportunities for process improvements specific to laboratory testing volume and services for continual quality improvement (e.g., contamination rate, workload and turnaround numbers/percentages over time, testing algorithms, equipment improvements/challenges). Report on the following information below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities related to improvements should be described.
- Progress, obstacles, and outcomes related to gained-efficiencies to previously stated objectives should be updated in subsequent annual performance reports.
- 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 will communicate and collaborate with partners (e.g., health care providers, TB Programs, TB Nurses, and other laboratories) to ensure optimal use of laboratory services and timely flow of information.

Laboratories should initiate plans for increased communication or educational opportunities for specimen collection and submission with TB Programs and other laboratories, find opportunities to apply evidence-based local practices within the broader public health system, and collaborate with TB Programs and local hospitals 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 below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities to improve communication and collaboration should be described.
- Progress, obstacles, and outcomes related to previously stated objectives should be updated in subsequent annual performance reports.
- Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

Carryover requests should be submitted as part of this report

For year 2 and beyond, recipients may request that estimated unobligated funds be carried over

into the next budget period. The carryover request must:

- Express a bona fide need for permission to use an unobligated balance.
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances).
- 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 2020, the Final report is due for year 2018). The Preliminary ARPE report is due for the current year minus one (for example, in 2020, the Preliminary report is due for year 2019). The report deadline was moved back from August 15 to March 31 to allow more current data to be used with the funding formula. The due dates for the Targeted Testing report for high morbidity areas follows the same schedule as the Contact Investigation report. Low morbidity areas are encouraged to report as indicated in Strategy 2c.

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. 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)

This report is due 90 days after the end of the period of performance. 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 project period, 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 $25,000.

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.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Glenroy Christie, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Deputy Branch Chief, Field Services Branch

Division of Tuberculosis Elimination

Centers for Disease Control and Prevention

1600 Clifton Road, NE. MS: US 12-4

Atlanta, GA 30333

Telephone: 404-639-8133

e-mail: gchristie@cdc.gov

Telephone: (404) 639-8133
Email: GPC5@cdc.gov

Grants Staff Contact

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

Louvern Asante, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
Grants Management Specialist Centers for Disease Control and Prevention

Infectious Diseases Branch (IDSB)

Office of Grants Services (OGS) Office of Financial Resources (OFR)

2939 Flowers Rd., MS: TV2

Atlanta, GA 30341

e-mail: LHA5@cdc.gov

phone: (770) 488-2835

For **laboratory technical assistance**, contact:

Angela Starks, Ph.D.

Chief, Laboratory Branch

Division of TB Elimination

Centers for Disease Control and Prevention

1600 Clifton Road, NE

Atlanta, GA 30333

Telephone: 404-639-3205

e-mail: astarks@cdc.gov

Email: astarks@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 attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Acceptable attachments continued:

- Organizational charts

- Other relevant documents such as Memorandum of Understanding or letters of support

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 http:// 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.
Assitance Listings (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.
Assistance Listings (CFDA) 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 project period. 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.
CDC Assurances and Certifications: Standard government-wide grant application forms.
Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established 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. http:// www.cdc.gov /grants /additionalrequirements /index.html.
DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.
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: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

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

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

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.

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 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).
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.
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: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.
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.
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

DST: Drug susceptibility test.

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.

MTBC: *Mycobacterium tuberculosis* complex.

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

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, direct high-performance liquid chromatography [HPLC]). This does not include rapid species identification tests performed on isolates such as ACCUPROBE.

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

TAT: Turnaround time.