
**Centers for Disease Control and Prevention**

Global Health Center

Innovative Approaches for TB Prevention and Case Finding to END TB

RFA-JG-25-137

03/03/2025

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## Overview

## Participating Organization(s)

Centers for Disease Control and Prevention

## Components of Participating Organizations

Components of Participating Organizations:
Global Health Center

## Notice of Funding Opportunity (NOFO) Title

Innovative Approaches for TB Prevention and Case Finding to END TB

## Activity Code

U01 – Research Project - Cooperative Agreements

## Notice of Funding Opportunity Type

New

## Agency Notice of Funding Opportunity Number

RFA-JG-25-137

## Assistance Listings Number(s)

93.494

## Category of Funding Activity

HL - Health

## NOFO Purpose

The World Health Organization’s (WHO) End TB Strategy envisions a world free of tuberculosis (TB)—zero deaths, disease, and suffering due to TB by 2035. This requires reducing the global TB incidence to <100 cases per million people within the next decade.

In 2022, an estimated 10.6 million people developed TB disease, and an estimated 1.3 million people died from TB. In 2022, 88% of all new TB cases were diagnosed in adults (≥15 years of

age), with 46% living in Southeast Asia, and 6.3% diagnosed in people living with HIV (PLHIV). Despite being preventable and treatable, large gaps in the detection and treatment of TB cases remain; about 4.2 million TB cases (40%) were not reported in 2021. These detection gaps are larger in populations at increased/higher risk for TB, including but not limited to children, persons with drug-resistant TB (DR-TB), people living with HIV and mobile and migrant populations.

Globally, it is estimated that 2 billion people (one-fourth of the world's population) may be infected with TB and contribute to future TB cases. Preventing TB transmission and increasing case finding is critical to achieving TB elimination goals.

The purpose of this Notice of Funding Opportunity (NOFO) is to develop, implement, and evaluate evidence-based and innovative approaches to halt progression of TB disease in high burden settings by improving identification and treatment of TB infection and TB disease, including sub-clinical TB, in all populations.

## Key Dates

**Publication Date:**
To receive notification of any changes to RFA-JG-25-137, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

**Letter of Intent Due Date:**
02/03/2025

**Application Due Date:**
03/03/2025

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 11:59 pm U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours:  Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with

application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

**Scientific Merit Review:**
04/09/2025

**Secondary Review:**
06/04/2025

**Estimated Start Date:**
09/30/2025

**Expiration Date:**
03/14/2025

## Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

**Note:**The Research Strategy component of the Research Plan is limited to 25 pages.

Page Limitations: Pages that exceed the page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

Applications that do not comply with these instructions may be delayed or may not be accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

## Executive Summary

Purpose: The purpose of this NOFO is to develop, implement, and evaluate evidence-based and innovative approaches under the following two thematic components:

- Component A - **Halt Progression of TB Disease:** Halt progression of TB disease in high-burden settings – with a focus on TB preventive treatment (TPT) with or without increased nutrition.
- Component B - **Case Finding and Course of TB Disease:** Detect TB infection and TB disease, including sub-clinical TB, using newer tools and products - in all populations including those at increased/higher risk for TB (i.e., PLHIV, children, displaced persons, healthcare workers, economically disadvantaged persons with other co-morbid conditions [alcohol use disorders, diabetes mellitus, persons who use illicit substances, undernourished], and older adults).

The anticipated total number of awards is up to 2, but only 1 award for each thematic component. Applicants may apply to one or both thematic components by submitting scientifically distinct and separate applications.

- *__Mechanism of Support:__ Cooperative Agreement
- *__Funds Available and Anticipated Number of Awards:__ The estimated total funding available, including direct and indirect costs, for the entire 5-year period of performance is $10,000,000 for both thematic components combined. The number of awards will be up to 2, one per thematic component. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- *__Budget and Period of Performance:__ The estimated total funding (direct and indirect) for the first year (12-month budget period) will be $2,000,000 with individual awards ranging from $0 to $1,000,000 per thematic component for the first year. The estimated total funding (direct and indirect) for the entire period of performance will be $10,000,000 for both thematic components combined. The project period is anticipated to run from 09/30/2025 to 09/29/2030.
- **Average One Year Award Amount:**
  $2,000,000
  The Approximate Total Fiscal Year Funding amount for Year 1 is $2,000,000. The expected number of awards is up to two.
  For this NOFO, applicants should apply to the Average One-Year Award Amount/Approximate Average Award amount of $1,000,000 instead of applying to the full $2,000,000 Approximate Total Fiscal Year Funding amount for Year 1. Applicants should develop a proposal to spend up to $1,000,000 for one thematic component. Applications proposing funding in excess of $1,000,000 for Year 1 per thematic component will be deemed “nonresponsive” and will not move forward to scientific peer review.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.

- **Number of Applications.** Applicant organizations may submit more than one application, provided that each application is scientifically distinct meaning that Component A and Component B are submitted as two different applications.
- **Application Type.** New
- **Special Date(s).** Letter of intent (LOI) date: February 3, 2025; Application receipt date: March 3, 2025. Applicants may submit their questions by e-mail to cgherpo@cdc.gov by 11:59 pm ET on December 12, 2024.
  Questions received after this time will not be considered for response. All changes, updates including the Q/A will be added as an amendment to the NOFO and will be posted on grants.gov within two weeks after December 12, 2024.
- **Application Materials.** See Section IV.1 for application materials

# Section I. Funding Opportunity Description

**Statutory Authority**
This program is authorized under Section 307 of the Public Health Service Act [42 USC 242l], as amended and Section 301(a) of the Public Health Service Act [42 USC 241(a)], as amended.

## 1. Background and Purpose

The End TB Strategy envisions a world free of TB, zero deaths, disease, and suffering due to TB by 2035. This requires reducing the global TB incidence to <100 cases per million people within the next decade [global TB incidence was 133 cases per 100,000 in 2022]. The End TB Strategy serves as a blueprint for countries to end the TB epidemic by driving down TB deaths, and incidence, and eliminating catastrophic costs (>20% of annual household income spent on TB costs). It outlines global impact targets to reduce TB deaths by 95% and cut new cases by 90% by 2035 (compared to 2015), as well as ensure that no family is burdened with catastrophic costs due to TB.

In 2022, an estimated 10.6 million people developed TB disease, and an estimated 1.3 million people died from TB. In 2022, 88% of all new TB cases were diagnosed in adults (≥15 years of age), with 46% living in Southeast Asia, and 6.3% diagnosed in PLHIV. Despite being preventable and treatable, large gaps in the detection and treatment of TB cases remain; only 6.4 million TB cases (60%) were officially reported in 2021. These detection gaps are larger in populations at increased/higher risks for TB, including but not limited to PLHIV, children, persons with DR-TB, and mobile and migrant populations.

Globally, it is estimated that 2 billion people (one-fourth of the world's population) may be infected with TB and contribute to future TB cases. Preventing TB transmission and infection and increasing case finding is critical to achieving TB elimination goals.

Although the number of people who developed DR-TB (multidrug-resistant TB [MDR-TB] and rifampicin-resistant TB [RR-TB]) was relatively stable between 2020 and 2022, there are substantial gaps in MDR/RR-TB detection and treatment. There were about 410,000 incident cases of MDR/RR-TB in 2022 with an estimated 3.3% as MDR/RR-TB.

Undernutrition is a major risk factor for TB with a 19% population attributable fraction – which is higher than HIV and diabetes. Undernutrition also leads to unfavorable TB treatment outcomes

and mortality. Additionally, it increases comorbidity with other key TB risk factors including HIV and alcohol use. Undernutrition can be treated safely and inexpensively.

Despite the enormous toll on health and well-being, the response to TB has been slow and underfunded, particularly around research with only half of the annual target reached. The third pillar of the End TB Strategy intensified research and innovation recognizes that achieving substantial reductions in TB incidence and mortality will require:

- Discovery, development, and rapid uptake of new tools, interventions, and strategies, including evaluations of new tests for TB infection and disease; and
- Research to optimize implementation and impact of new interventions including digital technologies.

The BCG vaccine has been around for almost a century. However, it does not provide adequate protection in adolescents and adults. Therefore, a new TB vaccine is a crucial prevention tool needed to End TB. There are several TB vaccine candidates under clinical development and about a dozen are in active trials. These trials cover a diverse candidate population including PLHIV, children, adolescents and adults.

This NOFO is **not intended** for animal research; basic biomedical research; nor biomarker, drug, device, or vaccine development.

**Healthy People 2030 and other National Strategic Priorities**

This NOFO aligns with CDC's current Global Health Strategy, including protecting Americans and populations across the globe by strengthening global public health prevention, detection, and response; saving lives, improving health outcomes, and fostering healthy populations globally; and leading the advancement of global public health science and serving as a leading source of credible scientific information.

This program addresses the "Healthy People 2030" focus area of the Global Health Goal: Improve health by preventing, detecting, and responding to public health events worldwide.

**Other Public Health Priorities and Strategies**

This NOFO aligns with the National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025 [carb-national-action-plan-2020-2025.pdf (hhs.gov)].

The U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (HHS/CDC) works with host countries and other key partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan and partnership framework. In an effort to ensure maximum cost efficiencies and program effectiveness, HHS/CDC also supports coordination with and among partners and integration of activities that promote Global Health Initiative principles. As such, recipients may be requested to participate in programmatic activities that include the following activities:

- Scale up evidence-based programs to identify and close the major TB gaps, among all populations at risk of TB infection and all forms of drug-sensitive and drug-resistant TB disease;
- Increase impact through strategic coordination and integration;
- Strengthen and leverage key multilateral organizations, global health partnerships, and private sector engagement;

- Encourage country ownership and invest in country-led plans;
- Build sustainability through investments in health systems;
- Enhance health equity and reduce disparities in access to and uptake of TB services;
- Assess demand, implementation readiness, and deployment strategies for next generation TB vaccines;
- Strengthen performance metrics, monitoring, and evaluation for program improvement; and
- Promote research, development, and innovation to develop a body of knowledge, enhance awareness, and increase the skills and abilities of partners.

Geographic prioritization may change over the course of the period of performance based on the burden of disease and evolving program priorities.

Any Personally Identifiable Information (PII) collected as part of the activities of this NOFO should be managed in a manner that protects individual-level data to the extent allowed by applicable law.

**Public Health Impact**

The health targets of the United Nations Sustainable Development Goals (SDGs) build on historic gains made under the United Nations Millennium Development Goals. The SDG target to “end the TB epidemic” by 2030 and more specifically the End TB Strategy include ensuring that no family is burdened with catastrophic expenses due to TB, and achieving a 90% reduction in TB deaths and an 80% reduction in TB incidence compared with levels in 2015, with targets for further reductions (95% and 90%, respectively) by 2035. However, there is still an enormous gap between current progress and the vision of the SDGs.

There is a need for public health research to deliver innovation for new and existing technologies, and to enable integrated people-centered prevention and case finding-approaches. The overall impact aimed through this NOFO is to develop, implement, and evaluate evidence-based and innovative approaches to halt the progression of TB disease. This will be done by identifying tools, strategies, and practices that can be incorporated into routine TB care in the future. Results from these innovative activities will provide local Ministries of Health and other key partners with the evidence base to support future adoption and scale-up of strategies that will maximize population-level impact of TB prevention efforts and TB case finding.

**Relevant Work**

CDC's global TB mission and strategies are aligned with the WHO's End TB Strategy, 2022 update, WHO’s Global Strategy for TB research and innovation (2020–2023), the Stop TB Partnership’s Global Plan to End TB (2023–2030), the United Nations SDGs for TB, and the 2018 and 2023 United Nations Political Declaration on the Fight Against TB. CDC works with technical organizations (Ministries of Health; the Global Fund to Fight AIDS, TB, and Malaria; and other U.S. agencies) to strengthen TB control programs to prevent, diagnose, and treat all forms of TB, including HIV-associated TB and drug-resistant TB.

Additionally, along with global partners, CDC TB experts are focusing on a distinct set of strategies as part of CDC's effort to decrease the incidence and mortality that TB causes globally:

- CDC protects Americans both domestically and abroad by working on the frontlines and providing expert technical advice, guidance, and training in high-burden TB and TB/HIV countries.
- CDC and partners are preventing TB transmission, by identifying TB hotspots for targeted screening, strengthening infection control practices in health facilities and communities, using early diagnosis and treatment as prevention, and scaling treatment to prevent TB among people who are at increased/higher risk for TB.
- CDC and partners are expanding access to better screening, improving case-finding approaches to identify new patients, enhancing testing strategies to optimize diagnostics, and providing training and technical support to scale accurate and reliable diagnostic tools.

In 2020, under the NOFO GH-20-001 titled, “Develop, Implement, and Evaluate Evidence-based, Innovative Approaches to Prevent, Find, and Cure Tuberculosis in High-Burden Settings”, CDC funded a five-year project titled, “Closing – TB GAPs – for people living with HIV: TB Guidance for Adaptable Patient-Centered Service.” TB GAPS aims to find and prevent TB in children and adolescents, while simultaneously determining the most cost-effective prevention strategy and promoting best practices to sustain impact, in five sub-Saharan African countries, including Eswatini, Lesotho, Malawi, Tanzania, and Uganda.

Selected publications related to the two research thematic components of the above referenced NOFO include:


- Bhargava, Anurag, et al. "Nutritional supplementation to prevent tuberculosis incidence in household contacts of patients with pulmonary tuberculosis in India (RATIONS): a field-based, open-label, cluster-randomised, controlled trial." The Lancet 402.10402 (2023): 627-640.
- Coussens, Anna K., et al. "Classification of early tuberculosis states to guide research for improved care and prevention: an international Delphi consensus exercise." The Lancet Respiratory Medicine (2024).
- Pai, Madhukar, Puneet K. Dewan, and Soumya Swaminathan. "Transforming tuberculosis diagnosis." Nature Microbiology 8.5 (2023): 756-759.
- Yanes-Lane, Mercedes, et al. "Tuberculosis preventive therapy for people living with HIV: A systematic review and network meta-analysis." PLoS Medicine 18.9 (2021): e1003738.
- Branigan, David. “2023 Pipeline Report: Tuberculosis Diagnostics.” Treatment Action Group (2023).


## 2. Approach

Research projects applied under this NOFO should reflect the applicant’s current and projected capacities and capabilities in implementing research to prevent TB transmission, find cases, and understand the spectrum of TB disease in high-burden TB settings and in all populations, including those who are at increased/higher risk for TB. Essential for the conduct of these activities is the institutional and investigator capacity necessary to perform this work. Applicants are encouraged to request support for the development of local research capacity necessary for the conduct of the proposed study/studies, and to propose studies that are feasible with maximum impact within the local capacity and context.

It is expected the research findings will be broadly disseminated and translated into public health practice to facilitate the development and implementation of new and better program models, or program improvement strategies, with immediate implementation within local communities of practice. There should be an opportunity to look at real-time data and the possibility of sharing early findings with programs to make real-time impact.

Recipient(s) will be expected to have the capacity to be able to conduct evaluation and research that assesses patient or population-level outcomes and the determinants and/or risk factors of those outcomes within clinical and community TB programs. Capacity in this context includes any necessary technical knowledge and skills required to support research activities (i.e., clinical, decentralized, and/or laboratory-based diagnostic expertise).

This NOFO includes two thematic components: Component A "Halt Progression of TB Disease" and Component B "Case Finding and Course of TB Disease." Objectives specific to each thematic component are stated below. Applicants may apply to one or both thematic components. If applying for both thematic components A and B, applicant must submit a scientifically distinct and separate application for each thematic component.

Application for each thematic component should be completed based on the application instructions in **Section IV**.

**Objectives/Outcomes**
The expected objectives for each thematic component are:

**COMPONENT A**

- **Halt Progression of TB Disease –** Break the cycle of TB transmission through prevention strategies focusing on TPT with or without nutritional support:
    - Develop and test innovative strategies to improve/optimize TPT regimens beyond PLHIV, including among TB contacts, healthcare workers, pregnant and breastfeeding women, and those with a risk of TB acquisition related to contact with TB patients.
    - Define the duration of TPT efficacy for different TB disease burden settings.
    - Assess the utility of repeat TPT, including after subsequent exposure.
    - Assess the impact of the combination of TPT and nutrition to prevent TB disease.
    - Explore and optimize innovative nutrition support strategies for TB disease prevention among those on TPT.
    - Assess financial and disease implications of nutrition support as TB disease prevention for those on TPT.

**COMPONENT B**

- **Case Finding and Course of TB Disease** – Improve/optimize case finding and understand the spectrum of TB disease:
    - Improve the quality and feasibility of contact tracing.
    - Use of innovative approaches like social networks for TB contact tracing and case finding.
    - Evaluate the effectiveness of new tools (e.g., artificial intelligence (AI), diagnostic tools and tests, etc.), algorithms, and strategies for screening and

diagnosis of TB in different settings (e.g., at different health entry points, communities, hotspots or high transmission areas, congregate settings, self-screening/testing, etc.).
    - Improve detection of the spectrum of TB disease and the impact of subclinical TB in disease transmission.
    - Understand the burden of post-TB lung disease and the extent to which TB is a contributing factor.

The **expected short-term outcomes** for each thematic component are:

**COMPONENT A**

- **Halt Progression of TB Disease**
    - Improved prioritization of patients for TPT based on the best combination of evidence-based risk factors.
    - Improved understanding of TPT effectiveness over time and across various populations.
    - Identification of feasibility and effectiveness of adding nutrition to TPT as an additional TB prevention strategy.
    - Measurement of cost-effectiveness and health outcomes of nutrition support programs for TB prevention.

**COMPONENT B**

- **Case Finding and Course of TB Disease**
    - Increased yield of screening
    - Increased yield of laboratory-confirmed and diagnosed cases
    - Increased and/or earlier TB treatment initiation among those diagnosed
    - Increased knowledge about the course of TB disease, the contribution of subclinical TB in disease transmission, the burden of post-TB lung disease, and the contribution of TB on post-TB lung disease

The **expected intermediate outcomes** for each thematic component are:

**COMPONENT A**

- **Halt Progression of TB Disease**
    - Reduced TB infection
    - Reduced incidence of TB disease

**COMPONENT B**

- **Case Finding and Course of TB Disease**
    - Improved bacteriological confirmation and case detection for all forms of TB
    - Increased TPT initiation among contacts
    - Increased and/or earlier TB treatment initiation among those diagnosed
    - Scale-up of strategies for contact tracing
    - Improved use of molecular WHO-recommended rapid diagnostics (mWRDs) through routine or novel practices
    - Scale-up of interventions to diagnose subclinical TB

- Identification and prediction of the progression of the disease
- Improved integration of new tools and tests into routine practice
- Adoption of successful approaches into national guidelines

The **expected long-term outcomes** for each thematic area are:

**COMPONENT A**

- **Halt Progression of TB Disease**
  - Reduced TB morbidity and mortality in high-burden settings and populations

**COMPONENT B**

- **Case Finding and Course of TB Disease**
  - Reduced TB morbidity and mortality in high-burden settings and populations

Applicants may propose other objectives with research activities, or outcomes from those listed above for each thematic component.

In furtherance of the underlying purposes of this NOFO, Recipient is expected to provide copies of and/or access to all data, software, tools, training materials, guidelines, and systems developed under this NOFO to Ministry of Health and other relevant stakeholders, including HHS/CDC, for appropriate use consistent with underlying authorities.

The project(s) should be registered at Home | ClinicalTrials.gov, as applicable.

**Population of Focus**
The CDC Division of Global HIV and Tuberculosis (DGHT), Global Tuberculosis Branch (GTB) focuses on specific countries where GTB can apply core strengths to maximize impact. For the purposes of this NOFO, applicants with experience, working relationships, and collaborative partners in one or more of the following countries (*__bold__ signifies a GTB priority country) are strongly encouraged to apply:

***Botswana**, Cambodia, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, ***Eswatini**, ***Ethiopia,** Ghana, ***Haiti**, ***India**, ***Kenya**, ***Lesotho**, ***Malawi**, ***Mozambique**, ***Namibia,** ***Nigeria,** Philippines, ***Rwanda**, ***South Africa**, South Sudan, ***Tanzania**, ***Uganda**, ***Vietnam**, ***Zambia**, and ***Zimbabwe**

CDC will only consider proposals including work in the countries listed above; if proposals include work in countries not listed above, they will not be considered for funding. Priority countries are high TB, drug-resistant TB (DR TB), and TB/HIV burden countries with a strong on the ground DGHT program presence. Proposals including work in countries signified as a GTB priority above (bolded with asterisk) will be preferred.

CDC encourages research proposals that are inclusive of all populations affected by TB without regard to race, ethnicity, gender identity, sexual orientation, and socioeconomic status. However, given that TB disproportionally affects some populations at increased/higher risk, proposals that include (but are not limited to) the following populations at increased/higher risk for TB will be prioritized: persons exposed to active TB disease (household contacts and social contacts), children, pregnant and breastfeeding women, PLHIV, racial and ethnic minorities, healthcare workers, older adults, migrants or mobile populations, and those with co-morbid health conditions that increase the risk for TB or complicate TB treatment and care (e.g., diabetes

mellitus, undernutrition, alcohol use disorders, substance use disorders, other respiratory diseases). Populations at increased/higher risk for TB may also include persons living in rural areas or underserved neighborhood, who often encounter barriers to accessing healthcare services. TB also intersects with a variety of social factors: including unstable housing, food security, poverty, incarceration, and inadequate education; proposals that account for these factors will also be prioritized.

**Collaboration/Partnerships**

The specific activities submitted as part of this NOFO should take place in high-burden TB settings. The recipient(s) will be expected to collaborate not only with CDC, but also with other partners, including (but not limited) to local Ministries of Health and WHO, to avoid duplication and promote synergies across proposed or planned activities. The recipient(s) will be expected to work closely with local and international agencies or organizations and other government entities responsible for engaging in the global elimination of TB.

Applicants should clearly specify how local partners will lead or assist these projects, how research capacity will be strengthened at local institutions, and how research findings will be disseminated to have maximum impact on public health.

**Evaluation/Performance Measurement**

The application should include measurable goals and aims based on a 5-year research project period. The recipient will establish specific, measurable, achievable, realistic, time-phased, inclusion, and equitable (SMARTIE) project objectives for each activity described in the application's project plan, and describe the development and implementation of project performance measures based on specific programmatic objectives.

The overall CDC Evaluation and Performance Measurement Strategy will focus on both process and outcome evaluation. Process evaluation is conducted to monitor activities during the implementation and operation of a program while an outcome evaluation examines the long-term successes and accomplishments of a program.

A plan for study activation visits (SAV) for each project to be conducted by the study team should be included with the application. The SAV is required to ensure that the proposed activities have met all regulatory requirements to begin the data collection phase of the research. The overall objective of the SAV is to assess the readiness level of the staff and research sites from the perspective of protection of human subjects and adherence to the research protocol. CDC staff will join the SAV.

A plan for ongoing monitoring of study activities should also be included in the application, including investigator monitoring of regulatory compliance, data quality, and laboratory quality, as applicable to the proposed research.

A timeline with measures of study progress should be described in the application. Progress towards those measures will be reported monthly, annually, and at project closeout.

Data use and data sharing agreements should be developed at the time of individual protocol development. It is expected all data should be de-identified and retained at CDC until all analyses are completed, and planned manuscripts are published. All data should be archived under the CDC retention policy guidelines.

**Translation Plan**

The application should include a timeline for completing the report of the main research findings and for developing and implementing a plan in collaboration with all relevant partners to disseminate the results/findings. This plan should include a process for sharing data, adapting project instruments and training materials that are relevant for programmatic use, and making these widely available to the Ministries of Health and other local partners, and to the global public health community. The plan should be specific to the project's objectives and be designed to ensure that the research findings can be utilized rapidly and broadly for maximum public health impact.

In addition, the recipient(s) will be expected to pursue dissemination avenues in public domains, such as workshops, regional meetings, and through informal channels (e.g., website, newsletters). Use of public health journals, as well as national and international conferences should be pursued to share with global TB partners to the greatest extent possible the best practices. Identified best practices could be used by other countries to improve their national TB programs for the total treatment cascade.

### 3. Funding Strategy

N/A

## Section II. Award Information

**Funding Instrument Type:**

CA (Cooperative Agreement)

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

**Application Types Allowed:**

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

**Estimated Total Funding:**

$10,000,000
Year 1: $2,000,000
Year 2: $2,000,000
Year 3: $2,000,000
Year 4: $2,000,000
Year 5: $2,000,000

**Anticipated Number of Awards:**

2

The Approximate Total Fiscal Year Funding amount for Year 1 is $2,000,000. The expected number of awards is up to two.

For this NOFO, applicants should develop a proposal to spend up to $1,000,000 for one thematic component per budget year. Applications proposing funding in excess of $1,000,000 for Year 1

per thematic component will be deemed “nonresponsive” and will not move forward to scientific peer review.

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

**Award Ceiling:**
$2,000,000
Per Budget Period

**Award Floor:**
$0
Per Budget Period

**Total Period of Performance Length:**
5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

# Section III. Eligibility Information

## 1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

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

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

Foreign Organizations: a Foreign Organization is a public or private organization, whether non-profit or for-profit, located in a country other than the United States (U.S.) and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the

state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR.

## 2. Foreign Organizations

Foreign Organizations **are** eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm UEI by viewing the organizational registration on SAM.gov. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

Foreign components of U.S. Organizations are eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

## 3. Additional Information on Eligibility

N/A

## 4. Justification for Less than Maximum Competition

N/A

## 5. Responsiveness

Any application that does not fully respond to the items in this section will be deemed "nonresponsive" and will not be moved forward for scientific peer review:

• If the application proposes funding in excess of $1,000,000 for the first year (12-month budget period) per thematic component and each subsequent 12-month budget period (direct and indirect).
• If the application is incomplete, meaning required elements of the application package are missing. The applicant will be notified that the application did not meet submission requirements.
• Late submissions will be considered non-responsive. See Part 1. Overview Information - Key Dates, for more information on Submission Dates and Time.
• Total amount of appendices should not include more than 50 pages. For this purpose, all appendices must have page numbers and must be clearly identified in the Table of Contents.

## 6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

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

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.

Grants.gov

eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

## 7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program

Directors/Principal Investigators do not need to register for a UEI number.

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its UEI number to the recipient organization.

## 8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

## 9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

## 10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

**Applicants may apply to one or both thematic components (A/B) by submitting scientifically distinct and separate applications.**
The applicant should make sure to title each of the applications to be distinctly different for the system to accept both the applications.
If more than one applicant from the same institute applies, there will only be one award made per institution to ensure diversity across recipients.

# Section IV. Application and Submission Information

## 1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

## 2. Content and Form of Application Submission

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 Application Guide to ensure you complete all appropriate “optional” components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

## 3. Letter of Intent

02/03/2025

Although a letter of intent is not required, is not binding, and does not enter into a review of a subsequent application, the information it contains allows CDC staff to plan the review. Prospective applicants are asked to submit a letter of intent by Feb 03, 2025 that includes the following information:

Name of the Applicant, Descriptive title of proposed research, Name, address, and telephone number of the PD(s)/PI(s), Names of other key personnel, Participating Institutions, Number and title of this funding opportunity.

Letter must be sent to:

Lata Kumar,

Director,

Extramural Research Program Office

Office of the Associate Director of Science

Global Health Center

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS H21-9

Atlanta, GA 30329

Email: lek7@cdc.gov

## 4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

## 5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation, and Approach. Describe the proposed research plan, including staffing and timeline.
4. **Progress Report Publication List** (for Continuation ONLY)

**Other Research Plan Sections**

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Other Plan(s)**
12. **Authentication of Key Biological and/or Chemical Resources**
13. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Other Plan(s) section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation. https://www.cdc.gov/grants/additional-requirements/ar-25.html

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

## 6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

## 7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

## 8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

**CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at** .How to Apply - Application Guide.

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

## 9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

**Note**: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/support
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.

**After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.**

**Unsuccessful Submissions**: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

03/03/2025
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

## 10. Funding Restrictions

**Expanded Authority:**

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

**Public Health Data:**

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

**Data Management Plan:**

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Other Plan(s) section of the PHS 398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

**Human Subjects:**

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to

conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

**Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.**

- **If the participating sites are within the United States: sIRB is required.**
- **If Foreign sites are participating in CDC-funded cooperative research studies: Each site is expected to get their own IRB from their performance sites.**

## 11. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

## 12. Other Submission Requirements and Information

**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 under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Please note the new requirement for a Risk Assessment Questionnaire (described above) that should be uploaded as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application.

**Application Submission**

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

**Applicants must complete all required registrations before the application due date.** Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

**Important reminders:**
All Senior/Key Personnel (including any Program Directors/Principal Investigators (PD/PIs) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

***It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.***

The applicant organization must ensure that the UEI number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

## Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://www.cdc.gov/about/divisions-offices/index.html), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

**Overall Impact**
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

**Scored Review Criteria**
Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance**
Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- Does the project address an important TB problem or a critical barrier to progress in TB prevention or case finding? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, services, or preventive interventions that drive TB prevention or case finding?
- Does the work address a scientific problem of great importance to public health research and/or practice in regard to making progress towards ending TB? What is the potential or actual impact of the research on the TB burden globally? Will the work be influential in that it will lead others to investigate the problem, open new areas of TB research, or change the scientific approach or public health practice, and how will this improve and be of value to public health? If successful, do the research results have the potential to be scalable and reach a large portion of the population at increased/higher risk for TB? Will the results reach a large portion of the population at increased/higher risk for TB?
- Is it clear that the project will accomplish the key objective of strengthening local implementation science research capacity, as evidenced by developing local principal investigators and strengthening local research institutions?

**Investigator(s)**
Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Are the Program Director/Principal Investigators (PD/PIs), collaborators, and other researchers well-suited to the project? Have they demonstrated an ongoing record of accomplishments record of accomplishments that have advanced TB research? If the project is collaborative or multi PD/PIs, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
- Do the investigators have well-established local in-country partners that will lead or assist the successful implementation of these projects? Have investigators described how research capacity will be strengthened at local institutions or locally, and how research findings will be disseminated to have maximum impact on public health? Will the local investigators have scientific leadership roles in research administration, design, protocol development, study implementation, publication of main study findings, and dissemination of results?
- Do the investigators have a successful and proven track record of publishing high-quality TB public health research in peer-review journals? Is there evidence of past and successful collaborations with the proposed research team? Have previous TB research results provided high-quality outputs and contributed to changes to policy and improvements in public health practice or population health?

**Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or evaluation or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Does the application challenge and seek to shift current public health practice paradigms or approaches? Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC? Does the project have the potential to increase efficiency or lead to cost savings?
- Does the application incorporate innovative approaches to directly strengthen capacity of one or more local research organizations?

**Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both

sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

- To what extent is the application scientifically distinct for the thematic component applied for?
- Are the overall strategy, methodology, and analyzes well-reasoned and appropriate to accomplish the specific aims of the project and completed in a timely manner? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and how will particularly risky aspects of the project be managed?
- If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- Does the application propose to use evidence-based interventions or strategies in the research plan? Does the strategy establish scalability? Is an evaluation plan included? Are outputs identified and are measures/metric to assess outcomes included? Is a translation plan included? Does the application describe how the results from the research will be disseminated and ultimately used?
- Will the approach to project funding, administration, development, and implementation clearly and directly strengthen the capacity of one or more local research partners to conduct research?

**Environment**
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

- Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- Does the project utilize critical partnerships or collaborations, especially at the local level? Does the project support key partner involvement throughout the research process?
- Does the project include collaborative research or is taking place in one or more GTB priority countries?

- Do the principal investigator and other key members of the project team have longstanding and successful participatory and collaborative arrangements with local research institutions and local partners implementing TB programs?

## 2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

**Protections for Human Subjects**
If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additional-requirements/ar-1.html).

**Inclusion of Women, Minorities, and Children**
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/women/research/index.htm) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).

**Vertebrate Animals**
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

**Biohazards**
Reviewers will assess whether materials or procedures proposed are potentially hazardous to

research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Dual Use Research of Concern**
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

## 3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

**Applications from Foreign Organizations**
Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

**Resource Sharing Plan(s)**
Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

**Budget and Period of Support**
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

The budget can include both direct costs and indirect costs as allowed.

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 modified total direct costs 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.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

## 4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

In addition to the above noted selection criteria, the following funding priorities will also be considered in making funding decisions.

**Funding Priorities**

- In making awards, funding decisions will attempt to achieve geographic diversity. To assure this, CDC will fund no more than one award per thematic component (component A or component B) per country.
- Research proposals that include animal research, basic biomedical research, biomarker, drug, device, or vaccine development **will not be** considered for funding.
- Funding preference will be given to those applications proposing research:

1. That includes work in countries listed below **will be** considered for funding.

    ***Botswana**, Cambodia, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, ***Eswatini**, ***Ethiopia,** Ghana, ***Haiti**, ***India**, ***Kenya**, ***Lesotho**, ***Malawi**,

***Mozambique**, ***Namibia, *Nigeria,** Philippines, ***Rwanda**, ***South Africa**, South Sudan, ***Tanzania**, ***Uganda**, ***Vietnam**, ***Zambia**, and ***Zimbabwe**

*Bold indicates a GTB priority country. Priority countries are high TB, drug-resistant TB (DR TB), and TB/HIV burden countries with a strong on the ground DGHT program presence.

2. That is located in at least one of the GTB priority countries (See bold countries above).
3. That includes several objectives under each thematic component.
4. That includes populations at increased/higher risk for TB as defined in the Target Population (Section I). These include (but are not limited to): Persons exposed to active TB disease (household contacts and social contacts), children, pregnant and breastfeeding women, PLHIV, racial and ethnic minorities, healthcare workers, older adults, migrants or mobile populations, and those with co-morbid health conditions that increase the risk for TB or complicate TB treatment and care (e.g., diabetes mellitus, undernutrition, alcohol use disorders, substance use disorders, other respiratory diseases).
5. That demonstrates a publication history of high-quality TB research supporting changes in policy or improve public health practice.

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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

### 5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

## Section VI. Award Administration Information

### 1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the recipient's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

### 2. CDC Administrative Requirements

**Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants.** See CDC General Terms and Conditions**.**

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

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-8: Public Health System Reporting Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-20: Conference Support

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

AR-22: Research Integrity

AR-23: Compliance with 45 C.F.R. Part 87

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

AR-28: Inclusion of Persons Under the Age of 21 in Research

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 -31 - Research Definition

AR 32 – FY 2012 Enacted General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Accessibility Provisions and Non-Discrimination Requirements are incorporated into CDC General Terms and Conditions

AR-35: Protecting Life in Global Health Assistance (AR-35) waived effective January 28, 2021

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

## 3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

**HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications:** This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

**Federal Funding Accountability and Transparency Act of 2006:** 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 grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

**Plain Writing Act:** The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: https://www.plainlanguage.gov/.

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

**Copyright Interests Provision:** This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Applicants may include reasonable publication costs and costs associated with submission, curation, management

of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. 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.

**Language Access for Persons with Limited English Proficiency:** Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

**Dual Use Research of Concern:** On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015, are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG-funding, or loss of future USG funding opportunities for the non-compliant USG-funded

research project and of USG-funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG-funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

**Data Management Plan(s):** CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additional-requirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

**Certificates of Confidentiality:** Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html.

## 4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

*__The PD(s)/PI(s) will have the primary responsibility for:__

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The recipient will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Overseeing all management, administrative, and scientific/programmatic aspects of the research including all data, resources, and operations.
- Providing the necessary personnel and supplies to implement the research activities and analyze the results.
- Collaborating with local senior researchers, CDC researchers, and community-based organizations or similar community liaison for the duration of the project period on several activities such as the development of the data-collection instruments, specimen - collection protocols, and data-management procedures.
- Working with HHS/CDC scientists to refine protocols to improve the study and other proposal components based on reviewers' comments in the summary statement.
- Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants, as determined by the study protocols and the research requirements.
- Following study participants as determined by the study protocols.
- Establishing procedures to maintain the privacy of the study participants and confidentiality of the research data.
- Agreeing to share data and specimens with CDC scientists, as well as appropriate international partners, such as the World Health Organization.
- In collaboration with HHS/CDC, present at national or international meetings and publish research findings in peer-reviewed scientific journals.

- Participating in conference with HHS/CDC project official(s) and research team; and attend in-person meetings with HHS/CDC co-investigators.
- Collaborating with USG agency scientists subject to U.S. Government rights of access consistent with applicable law and current DHHS, PHS, and CDC regulations, policies, and applicable bilateral agreements.
- Meeting the reporting requirements outlined in the Notice of Grant Award.
- Obtain and maintain the appropriate Institutional Review Board approvals for all institutions or individuals participating in research involving human subjects.
- Sharing all data and other project and programmatic information with CDC and the Ministry of Health upon request.
- Retaining custody of and having primary rights to the data and software developed under this award, subject to U.S. Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Submitting the study protocol and all protocol amendments, including any changes to the protocol, informed consent forms, data collection forms, and/or laboratory testing methods to the GTB Science Office and the engaged IRBs for review and approval. You must have CDC and IRB approval before the protocol and any amendments are implemented.
- CDC requires that the principal investigator submit copies of the study Adverse Event and Serious Adverse Event reports and all related correspondence to CDC as they are also submitted to the IRB. No patient or participant identifying information should be included on IRB reports and correspondence sent to CDC.
- Development of an Operations Manual that includes Standard Operating Procedures to ensure that all study staff members have written guidance to perform the specific study functions in accordance with the protocol.
- Required Training: All investigators should be familiar with Good Clinical Practice (GCP) requirements and have completed GCP training. Prior to study initiation and enrollment of participants, all investigators and study staff need to complete the following training requirements:

1. Human Subjects Protection Training. This training is mandatory for all Principal Investigators, Co-Investigators, and study personnel that have more than minimal involvement with the conduct of research or contact with research participants, confidential study data, subject records, or specimens. The following are a few sources for this training:

- NIH Protecting Human Research Participants (PHRP) web-based course: http://phrp.nihtraining.com/users/login.php
- Collaborative Institutional Training Initiative (CITI Program) web-based course: Research, Ethics, Compliance, and Safety Training (citiprogram.org)

2. Study Specific Training. Training of all study personnel on the protocol and study procedures is required prior to study initiation. The Principal Investigator is responsible for ensuring that adequate training records are maintained and available for review by CDC staff or its designate(s). The Investigator must also ensure all study staff are:

- Aware of regulatory requirements and acceptable standards for the conduct of clinical trials and the protection of human subjects

- Familiar with the purpose of the study and protocol
- Well-versed in protocol procedures and the attributes of the investigational product (if applicable)
- Trained and Competent to perform the assigned study tasks
- Informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate

3. International Air Transportation Association (IATA) Training (for studies requiring specimen air transport). Major carriers require that staff responsible for transport, shipping, or receipt of infectious substances undergo IATA training if blood products or specimens will be shipped. There is a fee associated with the training and a refresher course must be completed every two years. Additional information may be obtained at https://www.iata.org.

4. Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

***CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:**

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Monitor the cooperative agreement.
- Collaborate with recipient to establish priorities for the development and implementation of the recipient activities, both among and within each of the areas, through regular meetings and communication.
- Provide technical assistance to the recipient by linking them with other national and international agencies that might provide additional technical or material assistance.
- Collaborate as needed with funded institutions by providing technical assistance in support of activities implemented under this agreement.
- Collaborate with the funded institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies. Collaborate in development of a research protocol for IRB review by all collaborating institutions that are participating in the research project. Obtain and maintain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
- Provide technical assistance or advice on any information collections on 10 or more people that are planned or conducted by the awardee. All such information collections – where CDC staff will be or are approving, directing, conducting, managing, or owning

data – must undergo OMB project determinations by CDC and may require OMB PRA clearance prior to the start of the project.

- Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses. Based on this, HHS/CDC will make recommendations aimed at solving problems and at improving the quality and timeliness of the research activities.
- Provide consultation and guidance as needed in support of activities implemented under this agreement.
- Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.
- As the research sponsor for this study, the CDC Division of Global HIV and TB will provide oversight to ensure adherence to federal regulatory procedures for protection of human subjects and monitoring for protocol compliance.
- As the sponsor, CDC has the option of authorizing the initiation of research activities at each clinical site following completion of the SAV, and of periodically monitoring ongoing study activities for adherence to the study protocol, compliance with regulations for the protection of human subjects, and with the International Conference on Harmonization Good Clinical Practice (GCP) Guidelines, where applicable, either directly or through a contract research organization as its authorized representative. This assessment may include a review of patient flow, roles and training of on-site study staff, study documentation, and adherence to the protocol, including the procedures for administering informed consent and reporting adverse events. The monitor may also check the accuracy and completeness of data captured on the study forms.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

**Additionally, a Scientific Program Official in the Global Health Center Extramural Research Program Office (ERPO) will be responsible for the normal scientific and programmatic stewardship of the award as described below:**

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award; https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Serve as the primary point of contact on official award-related activities including an annual review of the recipient's performance as part of the request for continuation application;
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
- Carry out continuous review of all activities to ensure objectives are being met;
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitor performance against approved project objectives.

## 5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

**The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act),** includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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 recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

**A. Submission of Reports**

The Recipient Organization must submit:

**Annual Performance Report (APR)/RPPR** is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

**Annual Federal Financial Report (FFR) SF-425 (**Reporting | Grants | CDC ) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**

**Closeout Reports: a final progress report**, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance.**

**B. Content of Reports**

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

  b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

1. Principal Investigator is responsible for filing a monthly report to the project officer and DGHT Science Office, due by the 15th of the month for the period ending the prior month, to include a brief update on protocol development; the timeline for protocol review and approval; study status (e.g., not yet recruiting, recruiting, and enrollment complete), timeline, and enrollment figures).
2. The Principal Investigator is responsible for filing an annual report to the project officer and DGHT Science Office, to include a project summary; completed activities; remaining activities; abstracts and manuscripts submitted and published; funds expended and remaining; and timeline for completion of enrollment, data analysis, and dissemination.
3. The Principal Investigator is responsible for filing a close-out report to the project officer and the DGHT Science Office after the protocol has closed and the major study findings have been published. The close-out report includes a project summary, status with the IRBs, disposition of data, disposition of human biological materials; listing of dissemination activities; and description of the study impact.
4. The annual and closeout reports are reviewed by the DGHT Science Office which will make programmatic and budgetary recommendations.

**2. Annual Federal Financial Reporting** The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) 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 in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a Final FFR (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration

is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

**3. Final Reports:** Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The recipient's final report should include:

Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.

Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

## 6. Termination

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

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

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

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

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

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

## 7. 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.

## Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

**Application Submission Contacts**

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
https://www.grants.gov/support
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
https://www.era.nih.gov/need-help
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

**Scientific/Research Contact(s)**

Hammad Ali

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Anand Date

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**Peer Review Contact(s)**

Hylan Shoob

Center for Global Health (CGH), Office of Director

Telephone: 404-639-7618

Email: hms4@cdc.gov

**Financial/Grants Management Contact(s)**

Christina Park

Grants Management Officer

Office of Grant Services (OGS)

Telephone: 770-498-5014

Email: lsk1@cdc.gov

## Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

**Authority and Regulations**

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code of Federal Regulations.