Centers for Disease Control and Prevention

Center for Global Health Extramural Research Program Office

Develop, Implement, and Evaluate Evidence-based, Innovative Approaches to Prevent, Find, and Cure Tuberculosis in High-Burden Settings

RFA-GH-20-001

Application Due Date: 03/03/2020
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Part 1. Overview Information

Participating Organization(s)
Centers for Disease Control and Prevention

Components of Participating Organizations
Center for Global Health

Notice of Funding Opportunity (NOFO) Title
Develop, Implement, and Evaluate Evidence-based, Innovative Approaches to Prevent, Find, and Cure Tuberculosis in High-Burden Settings

Activity Code
U01

Notice of Funding Opportunity Type
New

Agency Notice of Funding Opportunity Number
RFA-GH-20-001

Assistance Listings (CFDA) Number(s)
93.947

Category of Funding Activity:
Health

NOFO Purpose

The 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 from >1250 cases per million people to <100 cases per million people within the next two decades.

Each year, an estimated 10 million people develop TB disease, and an estimated 1.6 million people die from TB – the leading cause of death from any infectious disease, including among people living with HIV (PLHIV). In 2017, 90% of all new TB cases were diagnosed in adults (15 years of age or older), and 9% were diagnosed in PLHIV with 72% living in Africa. Despite being preventable and treatable, large gaps in detection and treatment of TB cases remain; of the estimated 10 million new TB cases in 2017, only 6.4 million TB cases were officially reported. These detection gaps are larger in vulnerable populations, including but not limited to children, persons with MDR-TB, and mobile and migrant populations.

Drug-resistant TB is on the rise, posing significant programmatic challenges. Worldwide, an estimated 580,000 multi-drug-resistant (MDR) TB cases emerge annually. Unfortunately, there are substantial gaps in MDR TB detection and treatment. Approximately 1 out of 5 persons needing MDR TB treatment actually receive it, and among those who do receive treatment, less than half (48%) who start treatment finish successfully. These rates are driven by treatment failure, loss to follow-up, and premature death.

Globally, it is estimated that 1.7 billion people (about one fourth of the world’s population) are infected with TB and contribute to the reservoir of future TB cases. Expanding testing and treatment of TB infection is critical to achieving TB elimination goals. However, in high-burden countries, the implementation of TB preventive treatment (TPT) remains a low, or at the least,
competing priority.

The purpose of this Notice of Funding Opportunity (NOFO) is to develop, implement, and evaluate evidence-based and innovative approaches to:

- prevent TB infection, disrupt TB transmission, and halt progression of TB disease in high-burden settings;
- find TB infection and TB disease in all populations, including those most vulnerable (i.e., children, displaced persons, health care workers, economically disadvantaged, PLHIV, persons with other co-morbid conditions [alcohol use disorders, diabetes mellitus, persons who use illicit substances, undernourished] and elderly);
- optimize treatment for TB infection, TB disease, TB/HIV, and MDR TB through new treatment and adherence modalities;
- enhance and strengthen the use of routinely collected data to monitor, evaluate, and improve TB program performance; and
- implement operations research (i.e., local solutions for local problems) for broader application, adoption, and integration into routine TB care and treatment practice.

**Key Dates**

**Publication Date:**
To receive notification of any changes to RFA-GH-20-001, return to the synopsis page of this announcement at [www.grants.gov](http://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:**
02/03/2020

**Application Due Date:**
03/03/2020

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 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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: 04/20/2020
Secondary Review: 06/15/2020
Estimated Start Date: 09/30/2020
Expiration Date: 03/04/2020
Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

**ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED**

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) 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.

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

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

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 to:

- Prevent TB infection, disrupt TB transmission, and halt progression of TB disease in high-burden settings;
- Find TB infection and TB disease in all populations, including those most vulnerable;
- Optimize treatment for TB infection, TB disease, TB/HIV, and MDR TB through new treatment and adherence modalities;
- Enhance and strengthen the use of routinely collected data to monitor, evaluate, and improve TB program performance; and
• Implement operations research (i.e., local solutions for local problems) for broader application, adoption, and integration into routine TB care and treatment practice.

**Mechanism of Support:** Research Project – Cooperative Agreement

• **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire 5-year project period is $5,000,000. The number of awards will be up to two (2). Award(s) issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

• **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period 9/30/2020 to 9/29/2021) will be $1,000,000 with each individual award ranging from $0 to $1,000,000 for the first year. The estimated total funding (direct and indirect) for the entire project period will be $5,000,000. The project period is anticipated to run from 09/30/2020 to 09/29/2025

• **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.** The institutions/organizations listed in Section III.1 of this NOFO 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. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups 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. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.

• **Number of Applications:** Eligible applicant institutions may submit only one application.

• **Application Type:** New

• **Application Materials:** See Section IV.1 for application materials. Please note that Form E is to be used when completing the application package.

• **Special Dates:** LOI date: Feb 3, 2020; Receipt date: March 3, 2020. Applicants must submit their questions by e-mail to cgherpo@cdc.gov, within 15 days after the publication date of this NOFO in www.grants.gov. 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 a reasonable time.**
**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 from >1250 cases per million people to <100 cases per million people within the next two decades. The End TB Strategy serves as a blueprint for countries to end the TB epidemic by driving down TB deaths, incidence, and eliminating catastrophic costs. It outlines global impact targets to reduce TB deaths by 95% and cut new cases by 90% between 2015 and 2035, as well as ensure that no family is burdened with catastrophic costs due to TB.

TB is the leading cause of death from a single infectious agent globally; in 2017, TB was responsible for 1.6 million deaths. TB also ranks as the leading infectious disease cause of death in human history, claiming over a billion lives in the past two centuries alone.

Each year, an estimated 10 million people develop TB disease, and an estimated 1.6 million people die from TB — the leading cause of death from any infectious disease, including among PLHIV. In 2017, 90% of all new TB cases were diagnosed in adults (15 years of age or older), and 9% were diagnosed in PLHIV, with 72% living in Africa. Despite being preventable and treatable, large gaps in detection and treatment of TB cases remain; of the estimated 10 million new TB cases in 2017, only 6.4 million TB cases were officially reported. These detection gaps are larger in vulnerable populations, including but not limited to children, persons with MDR-TB, and mobile and migrant populations.

Drug-resistant TB is on the rise, posing significant programmatic challenges. Worldwide, an estimated 580,000 MDR TB cases emerge annually. Unfortunately, there are substantial gaps in MDR TB detection and treatment. Approximately 1 of 5 persons needing MDR TB treatment actually receive it, and among those who do receive treatment, less than half (48%) who start treatment finish successfully. These rates are driven by treatment failure, loss to follow-up, and premature death.

Globally, it is estimated that 1.7 billion people (about one fourth of the world’s population) are infected with TB and contribute to the reservoir of future TB cases. Expanding testing and treatment of TB infection is critical to achieving TB elimination goals. However, in high-burden countries, the implementation of TPT remains a low priority.

Despite this enormous toll on health and well-being, the response to TB has been slow and underfunded, particularly in the area of research. The third pillar of the End TB Strategy – research and innovation – recognizes that achieving substantial reductions in TB incidence and mortality will require the development, implementation, and evaluation of new tools and strategies, in addition to ensuring universal access to existing technologies and better use of those technologies. These include a rapid point-of-care test for diagnosing TB infection, TB disease, and detecting drug resistance; safer, shorter regimens for treating TB infection, drug-sensitive TB; shorter, safer and more effective treatment for drug-resistant TB; a new TB vaccine that is effective both before and after exposure; and innovative strategies to address the social and environmental drivers of TB.
This NOFO is **not intended** for animal research; basic biomedical research; nor drug, device, or vaccine development.

**Healthy People 2020 and other National Strategic Priorities**

This NOFO aligns with the current CDC strategic priorities including strengthening surveillance, epidemiology, and laboratory services; supporting public health activities; evaluating public health programs; conducting operational research; increasing global health impact; and preventing illness and death.

This program addresses the “Healthy People 2020” focus area of Global Health by improving public health through global disease detection, response, prevention, and control strategies.

**Other Public Health Priorities and Strategies**

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:

- Implement a woman- and girl-centered approach;
- 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 and strengthen metrics, monitoring, and evaluation for program improvement;
- Implement research, development, and innovation.

**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 World Health Organization’s (WHO) ‘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 reality 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, diagnosis, treatment, and care of TB.

The overall impact aimed for through this NOFO is to inform optimal program implementation through identifying ‘best practices’ and employing ‘local solutions to local problems’ for
broader application, adoption, and integration into routine TB care and treatment practices. Results from these activities will provide local ministries of health and other key stakeholders with the evidence base to support innovation, adoption, and scale-up of strategies that maximize population-level impact for all TB prevention, care, and treatment services, and strengthen local health systems.

**Relevant Work**

CDC's global TB mission and strategies are aligned with the WHO's End TB Strategy (2016–2020), the Stop TB Partnership's Global Plan to End TB (2016–2020), the United Nations SDGs for TB, the United Nations Political Declaration on the Fight Against TB, as well as the U.S. Government's Global TB Strategy, 2015–2019. CDC works with technical organizations (Ministries of Health; the Global Fund to Fight AIDS, TB, and Malaria; and other U.S. agencies) to support and strengthen TB control programs to find, cure, and prevent TB, 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 morbidity and mortality that TB causes globally:

- Protect Americans both here and abroad by being on the frontline and providing expert technical advice, assistance, and training in high-burden TB settings — CDC and its partners are expanding access to improved screening, contact tracing, and diagnostic tools to find the undiagnosed or "missing" cases. Many of these cases occur among the most vulnerable and hardest to reach populations including children, pregnant women, PLHIV, health care workers, and mobile and migrant populations. CDC and its partners are also evaluating new treatment regimens; working to expand access to care and treatment; breaking the cycle of transmission by strengthening infection control; implementing community-based approaches to targeting the hardest hit populations; and scaling-up more effective, and shorter treatment for TB infection, drug-sensitive and drug-resistant TB.
- Sustain countries' efforts to end the TB epidemic by helping countries to strengthen their surveillance and data translation capacity through promoting research capacity to support sustainable health systems.
- Find and combat TB and all its resistant forms — CDC is on the frontlines in some of the world's highest burden regions, working to understand what is driving the spread of drug-resistant TB and how to stop it.
- Increase access to effective TB prevention and treatment for those living with (or at risk for) HIV — CDC is leading global efforts to scale up TPT for PLHIV in President's Emergency Plan for AIDS Relief (PEPFAR)-funded countries.

**2. Approach**

Research projects applied under this NOFO should reflect the applicant’s current and projected
capacities and capabilities in implementing research to find, cure, and prevent TB in high-burden TB settings and in all populations, including those most vulnerable. 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, 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 in 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 for the prevention, care, and treatment of TB and TB/HIV.

Applicants should describe effective optimization of clinical and community TB prevention, care, and treatment services. Recipient(s) will be expected to have the capacity to be able to conduct evaluation and research which assess patient or population-level outcomes and the determinants and/or risk factors of those outcomes within clinical and community TB prevention, care, and treatment programs.

**Objectives/Outcomes**
Applicants may propose research focusing on one or more of the Prevent, Find, Cure, and Sustain focus areas. The expected objectives and examples of the type of research activities for each focus area are:

- **PREVENT** – Break the cycle of TB transmission through contact tracing, screening, and treatment for TB infection, as well as assuring effective TB infection control strategies are implemented in health care facilities. Activities may include (but are not limited to):
  - Implement and evaluate innovative strategies to improve/optimize access to TPT in all populations, including those most vulnerable.
  - Implement and evaluate innovative strategies to improve/optimize TPT regimens.
  - Collect and evaluate population-based data of risk-factors and biomarkers that facilitate the progression from TB infection to disease.
  - Implement and evaluate innovative strategies to prevent TB transmission to TB patients and health care workers in health care facilities.

- **FIND** – Implement and evaluate innovative strategies to improve/optimize finding active TB cases (all forms) and their contacts and linking them to care. Activities may include (but are not limited to):
  - Develop, implement, and evaluate novel diagnostic and treatment algorithms and approaches for contact investigation, screening, and diagnosis TB infection and TB disease in all populations, including those most vulnerable.
  - Develop innovative linkages between public and private health facilities to co-manage TB disease and TPT.
  - Implement and evaluate new and novel community-based case finding approaches using rapid diagnostic technologies.
  - Establish communities of practice for field-based TB outreach programs.

- **CURE** – Optimize TPT, drug-sensitive TB treatment, drug-resistant TB treatment, and
TB/HIV treatment or simultaneous treatment of TB with other co-morbid conditions (e.g., diabetes, alcohol use disorders, substance use disorders, non-tuberculous mycobacteria). Activities may include (but are not limited to):
- Evaluate and optimize new treatment regimens for all forms of TB (including TB infection).
- Evaluate and optimize the cascade of care for all forms of TB in varying settings of health care delivery (public, private, patient-centric models, clinic-centric models).
- Explore and evaluate new and innovative modalities to improve access to treatment for all forms of TB (including TB infection).
- Explore and evaluate new and innovative modalities to improve adherence support for all forms of TB (including TB infection) in varying settings of health care delivery (public, private, patient-centric models, clinic-centric models).
- Establish communities of practice for TB treatment and care in both public and private settings.

**SUSTAIN** – Improve the use of routinely collected data to monitor and evaluate TB program performance, and promote operations research (i.e., local solutions for local problems) for broader application, adoption and integration into routine TB care and treatment practice. Activities may include (but are not limited to):
- Strengthen surveillance and data translation capacity of national TB programs.
- Develop novel approaches for measuring progress against new WHO TB indicators.
- Use local data to identify local challenges, solve local problems, and develop local solutions.
- Establish communities of practice for data use, monitoring and evaluation, epidemiology, and operations research.

The expected short-term outcomes for each focus area are:

**PREVENT**
- Increased use of best practices for improved contact tracing
- Increased access to preventive care, including in Differentiated Service Delivery settings among PLHIV based on best practices
- Improved prioritization of patients for TPT based on best combination of evidence-based risk factors
- Increased use of best practices to prevent TB transmission to TB patients and health care workers in health care facilities

**FIND**
- Increased diagnosis for all forms of TB based on best modalities
- Improved linkages between private and public sector for the management of TB disease and TPT
- Increased best combination of novel diagnostics and approaches

**CURE**
- Improved linkage and access to TB services based on best practices
- Improved initiation of treatment regimens for all forms of TB based on best practices
- Improved adherence to TB treatment based on best modalities

**SUSTAIN**
- Increased use of evidence-based strategies for prevention, contact tracing, and case
finding
  o Improved approaches validated to measure progress against program indicators
  o Increased use of best practices for TB prevention, diagnosis and treatment

The expected intermediate outcomes for each focus area are:

- **PREVENT**
  - Reduced TB infection
  - Reduced incidence of TB disease
  - Communities of practice for TB prevention, care, and treatment established to translate innovative strategies into practice
- **FIND**
  - Improved case detection for all forms of TB
  - Increased case finding in public sector from private sector linkages
  - Communities of practice for field-based TB outreach programs established to translate novel and innovative approaches into practice
- **CURE**
  - Decreased gap between diagnosis and treatment for all forms of TB
  - Decreased time between diagnosis and treatment for all forms of TB
  - Increased completion of TB treatment
  - Communities of practice for TB treatment and care in both public and private settings established to translate new treatment regimens and new and innovative modalities into practice
- **SUSTAIN**
  - Increased case detection of all forms of TB
  - Increased translation of evidence into action, policy, guidelines, and practices
  - Increased use of validated approaches to measure progress against novel indicators
  - Communities of practice for data use, monitoring and evaluation, epidemiology, and operations research established to translate novel approaches and solutions into practice

The expected long-term outcomes for each focus area are:

- **PREVENT**
  - Reduced TB morbidity and mortality in high-burden settings and populations
- **FIND**
  - Reduced TB morbidity and mortality in high-burden settings and populations
- **CURE**
  - Improved treatment success rates for all forms of TB
  - Reduced incidence of drug-resistant TB cases
  - Reduced TB morbidity and mortality in high-burden settings and populations
- **SUSTAIN**
  - Improved use of data to inform and drive program improvement
  - Increased reliability in the measurement of progress using indicators towards attaining set targets
  - Reduced TB morbidity and mortality in high-burden settings and populations

Applicants may propose other objectives, type of research activities, or outcomes from those
listed above. However, for each proposed objectives, type of research activities, or outcomes, the focus should be on one or more of the Prevent, Find, Cure, and/or Sustain focus areas.

In furtherance of the underlying purpose of this announcement, Recipient is expected to provide copies 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 for appropriate use. CDC should be provided access consistent with applicable grants regulations.

**Target Population**
The CDC Division of Global HIV and Tuberculosis (DGHT), Global Tuberculosis Branch (GTB) has developed a strategic plan to prioritize and focus 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:


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. 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 disproportionately affects some vulnerable populations, proposals that include (but are not limited to) the following vulnerable populations will be prioritized: persons exposed to active TB disease (household contacts and social contacts), children, racial and ethnic minorities, health care workers, elderly, PLHIV, migrants or mobile populations, and those with co-morbid health conditions that exacerbate TB treatment and care (e.g., diabetes mellitus, malnutrition, alcohol use disorders, substance use disorders, other respiratory diseases). Vulnerable populations may also include persons living in rural areas or slums, who often encounter barriers to accessing health care 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 listed in 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 strategies of malaria.

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(s) will establish specific, measurable, achievable, realistic and time-phased (SMART) 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. Recipient(s) should expect to be joined on the SAV by CDC staff.

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 (Section VI).

Data use and data sharing agreements shall be developed at the time of individual protocol development. It is expected all data shall be de-identified and retained at CDC until all analyses are completed, and planned manuscripts are published. All data shall 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 stakeholders 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 for making these widely available to the ministry(s) 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 to prevent, find, and cure TB and sustain TB programs. Identified best practices could be used by other countries to improve their national TB programs for the total treatment cascade.

**Section II. Award Information**

**Funding Instrument Type:** 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:** $5,000,000

**Estimated Total Annual Budget Period Funding for each award:**

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

**Estimated total funding available for first year (first 12 months), including direct and indirect costs for each award:** $1,000,000

**Estimated total funding available for entire project period, including direct and indirect costs:** $5,000,000

**Anticipated Number of Awards:** 2

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

Throughout the project period, CDC's commitment to continuation of awards will be conditional on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award ceiling and floor are for the first 12-month budget period only.

**Award Ceiling:** $1,000,000 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 ([http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.pdf](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.pdf)) will apply to the applications submitted and awards made in response to this NOFO.

### Section III. Eligibility Information

#### 1. Eligible Applicants

| Eligibility Category | County governments | City or township governments | Special district governments | Independent school districts | Public and State controlled institutions of higher education | Native American tribal governments (Federally recognized) | Public housing authorities/Indian housing authorities | Native American tribal organizations (other than Federally recognized tribal governments) | Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education | Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education | Private institutions of higher education | For profit organizations other than small businesses | Small businesses | Others (see text field entitled "Additional Information on Eligibility" for clarification) |
|----------------------|---------------------|-----------------------------|-----------------------------|-----------------------------|------------------------------------------------|----------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|------------------------------------------------|-----------------------------|-----------------------------|------------------------------------------------|

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

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<th>2. Foreign Organizations</th>
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<td>Foreign Organizations are eligible to apply.</td>
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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 DUNS by sending an e-mail to ecrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135/Public/Docs/US%20Instructions%20for%20NSP%20NCAGE.pdf.

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.

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<th>4. Justification for Less than Maximum Competition</th>
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<th>5. Responsiveness</th>
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<td>Responsiveness:</td>
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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 Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nsp.a.nato.int/AC135Public/Docs/US%20Intructions%20for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- 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 Program Directors/Principal Investigators (PD/Pis) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle 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 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 DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](http://www.dnb.com) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. 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 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 the SAM internet site at [https://www.sam.gov/index.html](https://www.sam.gov/index.html).

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 DUNS number to the recipient organization.

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

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

### 9. Cost Sharing

This FOA 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](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](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.

Only one application per institution (normally identified by having a unique DUNS number) is
Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist 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:
   · E-mail: http://grants.nih.gov/support/index.html
   · Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, 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 (R&R) 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.

Letters of Support from partner companies or organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Please include all of the eight (8) mandatory forms listed below in the application package:

**Mandatory**

1. SF424(R&R)[V2.0];
2. PHS 398 Cover Page Supplement [V4.0];
3. Research and Related Other Project Information [V1.4];
4. Project/Performance Site Location(s) [V2.0];
5. Research and Related Senior/Key Person Profile (Expanded) [V2.0];
6. Research and Related Budget [V1.4];
7. PHS 398 Research Plan [V4.0];
8. PHS Human Subjects and Clinical Trials Information [V1.0].

Please include the one (1) optional form listed below, if applicable, in the application package:

Optional

1. R&R Sub-award Budget Attachment(s) Form 5 YR 30 ATT.

3. Letter of Intent

Due Date for Letter of Intent: **02/03/2020**

**LOI is mandatory for this NOFO and would be required to submit by the due date listed above.**

By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent 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 announcement

The letter of intent should be sent to:

Lata Kumar
Extramural Research Program Office
Office of the Associate Director of Science
Center for Global Health
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS D-69
Atlanta, GA 30333
Fax: 404.639.7490
Email: lkumar@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 [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf) and [http://grants.nih.gov/grants/how-to-apply-application-guide.htm](http://grants.nih.gov/grants/how-to-apply-application-guide.htm) 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 time line.
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. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan 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, or limitations to, 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);
• 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).


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 publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

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.

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** [https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf).

### 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. Organizations must submit applications using the ASSIST web-based application preparation and submission process.

ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted. **Applicants are responsible for viewing their application 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 resubmitted in ASSIST.**

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


**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


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/web/grants/support.html](https://www.grants.gov/web/grants/support.html)

[support@grants.gov](mailto: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.

**Due Date for Applications:** 03/03/2020

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

### 10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http://www.whitehouse.gov/omb/grants_spoc).

### 11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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. In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html). 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. 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. 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 Resource Sharing Plan(s) section of the PHS398 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, privacy and confidentiality considerations, embargo issues). 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/additionalrequirements/ar-25.html for revised AR-25.

Restrictions, which must be taken into account while writing the budget, are as follows:

- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Indirect costs on grants awarded to foreign organizations and foreign public entities, and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization. Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities).
- The applicant may contract with other organizations under this program; however, the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of services for which funds are required).
- All requests for funds contained in the budget, shall be stated in U.S. dollars (USD). Once an award is made, CDC will not compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.
- Funds for research involving human subjects will be restricted until the appropriate Federal-wide Assurance and all Institutional Review Board Approvals are in place.
- Foreign recipients are subject to audit requirements specified in 45 CRF 74.26(d). A non-Federal audit is required, if during the recipient’s fiscal year, the recipient expended a total of $300,000.00 or more under one or more HHS awards (as a direct recipient
and/or as a sub-recipient). The recipient either may have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements obtained in OMB Circular A-133.

- A fiscal Grantee Capability Assessment may be required, prior to or post award, in order to review the applicant’s business management and fiscal capabilities regarding the handling of U.S. Federal funds.
- Recipients may purchase equipment and complete minor renovations if deemed necessary to accomplish the research objectives in accordance with applicable federal law and HHS/CDC policy; however, recipients must request prior approval by HHS/CDC officials in writing and conduct procurements in a transparent and competitive manner.

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

- Recipients may not use funds for clinical care except as allowed by law
- Generally, recipients may not use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. Any such proposed spending must be clearly identified in the budget in accordance with CDC’s budget guidelines.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
  o Publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat enactment of legislation before any legislative body.
  o The salary or expenses of any grant of contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body.
  o See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients. Other than for normal and recognized executive-legislative relationships, no funds may be used for:

Additional Funding Restrictions:

1) 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.

2) On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on
When EIN authorized NOFO, documents supporting https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf 1132 CDC for per limited review https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf conditions, such to CDC Risk Management Requirements described 3) regulations. institution, USG-funded funding, or loss of future US Government (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.

3) Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this NOFO (https://www.cdc.gov/grants/additionalrequirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

12. Other Submission Requirements and Information
Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant’s CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant’s history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not pay list; and System for Award Management (SAM) exclusions.
CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. If your organization has completed CDC’s Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization’s EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application
package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

**Duplication of Efforts**
Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual’s time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual’s effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report 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_redir ect.htm? id=11144).

**Important reminders:**
All 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.

The applicant organization must ensure that the DUNS 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:

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (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.

**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 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.

The applicant organization must ensure that the DUNS 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
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 ([http://www.cdc.gov/about/organization/mission.htm](http://www.cdc.gov/about/organization/mission.htm)), 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 clinical practice 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 care and prevention? 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, treatments, services, or preventive interventions that drive TB care and prevention?
Does the work address a scientific problem of great importance to public health research and/or practice in regards to TB? What is the potential or actual impact of the research on the TB burden in the US and 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 risk?

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 PD/Pis, collaborators, and other researchers well-suited to the project? Have they demonstrated an ongoing and proven record of accomplishments that have advanced TB research? 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?

Do the investigators have well-established local in-country partners that will lead or assist these projects? Have investigators described how research capacity will be strengthened at local institutions, 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 improvements in public health practice, changes to policy, and 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 project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects 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?

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 project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects 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?

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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 stakeholder involvement throughout the research process?

Does the project include collaborative research in one or more of GTB focus 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/additionalrequirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

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/maso/Policy/Policy_women.pdf) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

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/VASchecklist.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)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a
detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

• 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, or limitations to, 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);
• 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 de-identified data).

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.

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 guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinappplying/applicationresources.html

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 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.


Proposals that include work in countries not listed above will not be considered for funding. *Bold* indicates a GTB priority country.

Funding preference will be given to those applications which:

1. Propose research that has potential for cross-cutting impact on all GTB focus areas of Prevent, Find, Cure, and Sustain.
2. Propose research that includes vulnerable populations as defined in the Target Population (Section 1).
3. Propose research located in at least one of the GTB priority countries (See bold countries above).
4. Demonstrate a publication history of high-quality TB research.
5. In making awards, funding decisions will attempt to achieve geographic diversity. To assure this, CDC will fund no more than one award per country. If additional funding becomes available, CDC will have the option to fund a second award per country.

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

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

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in
this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior
recipient of Federal awards, including timeliness of compliance with applicable reporting
requirements, conformance to the terms and conditions of previous Federal awards, and if
applicable, the extent to which any previously awarded amounts will be expended prior to
future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and
findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements
imposed on non-Federal entities.

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

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 DUNS, 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

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 grantee’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
   Administrative and National Policy Requirements, Additional Requirements (ARs) outline the
administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and
other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: [http://www.access.gpo.gov/nara/cfr/cfr-table-search.html](http://www.access.gpo.gov/nara/cfr/cfr-table-search.html).

Specific requirements that apply to this NOFO are the following:

Specific requirements that apply to this NOFO are the following:

1. **Recipient Evaluation and Performance Measurement Plan**

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

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.
- How data will be reported.
- How evaluation findings will be used to ensure continuous quality improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement. Where applicable, this includes support for, and response to, activities associated with the Site Monitoring System and implementation of Data and Service Quality Assessments.

2. **Performance Measure Reporting**

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

The recipient is responsible for managing and monitoring each project, program, sub-award, function or activity supported through this Agreement. Recipients must monitor sub-awards to ensure that sub-recipients have met the programmatic impact requirements as set forth in the sub-recipient’s agreement.
3. Audit, Books, and Records

A. Reports and Information. The recipient must furnish HHS/CDC accounting records and such other information and reports relating to the Agreement as HHS/CDC may reasonably request.

B. The Recipient Agreement Books and Records. The recipient must maintain accounting books, records, documents and other evidence relating to the Agreement, adequate to show, without limitation, all costs incurred by the recipient, the receipt and use of goods and services acquired by the recipient, agreed-upon cost sharing requirements, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the recipient, the basis of award of recipient contracts and orders, and the overall progress of the Agreement toward completion ("Agreement books and records"). The recipient must maintain Agreement books and records in accordance with generally accepted accounting principles prevailing in the United States, or at the recipient’s option, with approval by HHS/CDC, other accounting principles, such as those (1) prescribed by the International Accounting Standards Committee (an affiliate of the International Federation of Accountants), or (2) prevailing in the country of the recipient. Agreement books and records must be maintained for at least three years after the date of last disbursement by HHS/CDC or for such longer period, if any, required to resolve any litigation, claims or audit findings.

C. Partner Government Audit. If $300,000 or more of US Government funds are expended by the recipient in its fiscal year under the Agreement, the recipient must have financial audits made of the expenditures in accordance with the following terms, except as the Parties may otherwise agree in writing:

1. The recipient must use its Supreme Audit Institution (SAI), if the SAI is approved by HHS/CDC, or select an independent auditor to perform the audit in accordance with the guidelines issued by HHS/CDC.
2. The audit must determine whether the receipt and expenditure of the funds provided under the Agreement are presented in accordance with generally accepted accounting principles agreed to in Section 2 above and whether the recipient has complied with the terms of the Agreement.
   Each audit must be submitted to HHS/CDC no later than nine months after the close of the recipient’s year under audit.

D. Sub-recipient Audits. The recipient, except as the Parties may otherwise agree in writing, must ensure that “covered” sub-recipients, as defined below, are audited, and submit to HHS/CDC, no later than the end of the recipient’s year under audit, in form and substance satisfactory to HHS/CDC, a plan for the audit of the expenditures of "covered" sub-recipients, as defined below, that receive funds under this Agreement pursuant to a direct contract or agreement with the recipient.

1. "Covered" sub-recipient is one who expends $300,000 or more in its fiscal year in "US Government awards" (i.e. as recipients of US Government cost reimbursable contracts, grants or cooperative agreements).
2. The plan must describe the methodology to be used by the recipient to satisfy its audit responsibilities for covered sub-recipients. The recipient may satisfy such audit responsibilities by relying on independent audits of the sub-recipients; expanding the scope of the independent financial audit of the recipient to encompass testing of sub-recipients' accounts; or a combination of these procedures.

3. The plan must identify the funds made available to sub-recipients that will be covered by audits conducted in accordance with audit provisions that satisfy the recipient’s audit responsibilities.

4. The recipient must ensure that covered sub-recipients under direct contracts or agreements with the recipient take appropriate and timely corrective actions; consider whether sub-recipients' audits necessitate adjustment of its own records; and require each such sub-recipient to permit independent auditors to have access to records and financial statements as necessary.

E. Audit Reports. The recipient must furnish or cause to be furnished to HHS/CDC an audit report for each audit arranged for by the recipient in accordance with this Section within 30 days after completion of the audit and no later than nine months after the end of the period under audit.

F. Cost of Audits. Subject to HHS/CDC approval in writing, costs of audits performed in accordance with the terms of this Section may be budgeted for, and charged to, the Agreement so long as such costs are allowable, allocable, and reasonable as defined in the Cost Allowability section of this Agreement.

G. Audit by HHS/CDC. HHS/CDC retains the right to perform the audits required under this Agreement on behalf of the recipient conduct a financial review, or otherwise ensure accountability of organizations expending US Government funds regardless of the audit requirement.

H. Opportunity to Audit or Inspect. The recipient must afford authorized representatives of HHS/CDC the opportunity at all reasonable times to audit or inspect activities financed under the Agreement, the utilization of goods and services financed by HHS/CDC, and books, records and other documents relating to the Agreement.

I. Sub-recipient Books and Records. The recipient will incorporate paragraphs (1), (2), (4), (5), (6), (7) and (8) of this provision into all sub-agreements with non-U.S. organizations which meet the $300,000 threshold of paragraph (3) of this provision. Sub-agreements with non-U.S. organizations, which do not meet the $300,000 threshold, must, at a minimum, incorporate paragraphs (7) and (8) of this provision. Sub-agreements with U.S. organizations must state that the U.S. organization is subject to the audit requirements contained in OMB Circular A-133.

4. Reporting of Foreign Taxes

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) Sub-agreements. The recipient must include this reporting requirement in all applicable sub-grants and other sub-agreements.

5. Final Report

The final report reporting progress on the entire project period 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, health care 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 project period. 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.

The Principal Investigator is responsible for filing a close-out report to the project officer and the GTB 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 study impact.

Generally applicable ARs:

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-17: Peer and Technical Reviews of Final Reports of Health Studies &ndash; ATSDR
AR-18: Cost Recovery &ndash; ATSDR
AR-19: Third Party Agreements &ndash; ATSDR
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: Policy on Public Health Research and Non-research 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, &ldquo;Federal Leadership on Reducing Text Messaging while Driving&rdquo;, October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR 32 &ndash; FY 2012 Enacted General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Language Access for Persons with Limited English Proficiency
AR-36: Certificates of Confidentiality
ARs applicable to HIV/AIDS Awards:

**AR-4: HIV/AIDS Confidentiality Provisions**

**AR-5: HIV Program Review Panel Requirements**

**AR-6: Patient Care**

[SEB(1)]CGH ERPO- we typically use these ARs in our NOFOs:

The following administrative requirements apply to this project:

Generally applicable administrative requirements (ARs):

- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010, P.L. 111-274
- AR-34: Affordable Care Act, P.L. 111-148

ARs applicable to Center for Global Health Assistance Awards:

- AR-35: Protecting Life in Global Health Assistance

ARs applicable to HIV/AIDS Awards:

- AR-5: HIV Program Review Panel
- AR-6: Patient Care

Organization Specific ARs:

- AR-8: Public Health System Reporting (Community-based non-governmental organizations)
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-15: Proof of Non-profit Status (Non-profit organizations)
• AR 23: Compliance with 45 C.F.R. Part 87 (Faith-based organizations)

Potentially Applicable Public Policy Requirements

• False or Misleading Information
• Taxes: Certification of Filing and Payment of Taxes
• Fly America Act/ U.S. Flag Air Carriers
• National Environmental Policy Act

If applicable, award recipients will be required to submit an electronic version of the final, peer-reviewed manuscript of any work developed under this award upon acceptance for publication. Additional information will be provided in the award terms.

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 apply 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: http://www.plainlanguage.gov/plLaw/index.cfm.

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

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. Pursuant to applicable grant regulations and CDC’s Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient’s submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient’s submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision. The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

**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 the 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. Grantees (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 new 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/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/additionalrequirements/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/additionalrequirements/ar-36.html](https://www.cdc.gov/grants/additionalrequirements/ar-36.html).

### 4. Cooperative Agreement Terms and Conditions

- 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].
- Recipients 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) web-based course:
  http://citiprogram.org/ Family Health International Research Ethic Training Curriculum:

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 http://iata.org [CU2].

4. Recipients 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 recipient. 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

Areas of Joint Responsibility:

- All responsibilities are divided between recipients and CDC staff as described above.

**CDC Program Support to Recipients**

In a cooperative agreement, CDC staff are substantially involved in the program activities,
above and beyond routine grant monitoring. CDC activities for this program are as follows:

1. Review and approve the recipient’s monitoring and evaluation plan
2. Meet on a regular basis with the recipient to assess expenditures in relation to approved
work plan and modify plans as necessary.
3. Meet on a regular basis with the recipient to assess technical and financial progress
reports and modify plans as necessary.
4. Provide technical assistance, as mutually agreed upon, and revise annually during
validation of the first and subsequent annual work plans. This could include expert
technical assistance and targeted training activities in specialized areas.

5. Collaborate with the recipient on designing and implementing the activities listed above, including, but not limited to: the provision of technical assistance to develop research activities, data management and analysis, quality assurance, the presentation and possibly publication of research results and findings, and the management and tracking of finances.

6. Assist the recipient in developing and implementing quality-assurance criteria and procedures.

7. Facilitate in-country planning and review meetings for technical assistance activities.

8. Provide technical oversight for all research activities under this award.

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.


Additional reporting requirements:

1. Principal Investigator is responsible for filing a monthly report to the project officer and GTB 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 GTB 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 GTB 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 GTB Science Office which will make programmatic and budgetary recommendations.

A. Submission of Reports
The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form ([https://grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm); [https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf](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.


3. A final progress report, invention statement, equipment/inventory report, and the final FFR are required 90 days after the end of the period of performance.

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:

   - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons
Lesson 1: Research Leadership/Partnership: This section 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?

Lesson 2: 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 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 contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

Lesson 3: 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. **Yearly Non-Competing Grant Progress Report:** The recipient’s continuation application/progress report should include:
   - Description of Progress during Annual Budget Period: Current Budget Period Progress reported via RPPR. Complete all sections of the RPPR online via eRA Commons.
   - Research Aims: list each research aim
     - 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, health care 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 contributed to documented or projected reductions in morbidity, mortality, injury, disability or disease?

* Within 90 days after the end of each budget period (each budget period within the project period), the Recipient will update the annual RPPR submitted as part of the continuation application for the previous budget period to ensure the progress report comprehensively reports the progress of activities throughout the entire budget period. The Recipient will share the updated RPPR with CDC within 90 days after the end of each budget period.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information 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.

The due date for final FFRs will continue to be 90 days after the Period of Performance end date.

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, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. 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).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_frr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://commons.era.nih.gov/commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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 grantee’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.

### 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
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
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

**Scientific/Research Contact(s)**
Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at [www.grants.gov](http://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 Federal Regulations.