

Centers for Disease Control and Prevention

Center for Global Health

Enhancing Capacity for Strategic and Applied Research Activities in Support of Control and Elimination of Malaria and Other Parasitic Diseases

RFA-GH-22-001

03/01/2022

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Overview
Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

Center for Global Health

Notice of Funding Opportunity (NOFO) Title

Enhancing Capacity for Strategic and Applied Research Activities in Support of Control and Elimination of Malaria and Other Parasitic Diseases

Activity Code

U01

- Amendment 1: Summary of Changes
    - Section VIII. Questions received during Q&A period, and answers added
    - Section I. Funding Opportunity Description:
        - Part 1. Background and Purpose has been amended to read as follows
            - Category 2: Malaria in Sub-Saharan Africa' [page **7 of 52**], "In coordination with global partners, evaluate community-level case management activities and practices for severe and **un**complicated malaria to strengthen the ability of health facilities and community intervention efforts to provide timely and appropriate care and treatment to vulnerable populations (Focus for Year 1).
            - [Page **6 of 52**]: "An applicant applying for Category 1 should focus their Year 1 activities on the key goals (#1 **and/or** #2)
            - [Page **7 of 52**]: "An applicant applying for Category 2 should focus their Year 1 activities on the key goals (#1 **and/or** #2)
        - Part 2. Approach' under 'Approaches for Category 2. Malaria', Approach #1 [page **10 of 52**], has been amended to read as follows: "Evaluate

community-level case management activities and practices for severe and **un**complicated malaria (focus for year 1)."

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-GH-22-001

Assistance Listings Number(s)

93.326

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this notice of funding opportunity (NOFO) is to assist with the implementation of research studies that will provide critical information on ways to monitor, control, and potentially eliminate parasitic diseases including malaria. Through this funding announcement, the Division of Parasitic Diseases and Malaria seeks to fund critical research and evaluation activities with the potential to yield high impact public health findings and to improve strategies that will decrease the overall burden of parasitic diseases and increase the health and wellbeing of affected populations. Research topics include identifying and tracking morbidity, developing and testing better diagnostic tools, improving surveillance, and developing and evaluating interventions that can reduce or interrupt transmission of parasitic diseases including reduction of their vectors. This is a 2-category research NOFO – Category 1: Schistosomiasis and/or Soil-Transmitted Helminths in Kenya, and Category 2: Malaria in sub-Saharan Africa. Applicants can only apply for 1 category. If an applicant applies to both categories, their applications will not move forward for review and consideration of funding.

Key Dates

Publication Date:

To receive notification of any changes to RFA-GH-22-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:

02/01/2022
02/01/2022

Application Due Date:

03/01/2022
03/01/2022

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.

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

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

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

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

Scientific Merit Review:
04/05/2022

Secondary Review:
05/03/2022

Estimated Start Date:
09/30/2022

Expiration Date:
09/29/2022

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose:** The purpose of this notice of funding opportunity (NOFO) is to assist with the implementation of research studies that will provide critical information on ways to monitor, control, and potentially eliminate parasitic diseases including malaria. Through this funding announcement, the Division of Parasitic Diseases and Malaria seeks to fund critical research and evaluation activities with the potential to yield high impact public health findings and to improve strategies that will decrease the overall burden of parasitic

diseases and increase the health and wellbeing of affected populations. Research topics include identifying and tracking morbidity, developing and testing better diagnostic tools, improving surveillance, and developing and evaluating interventions that can reduce or interrupt transmission of parasitic diseases including reduction of their vectors. This is a 2-category research NOFO – Category 1: Schistosomiasis and/or Soil-Transmitted Helminths in Kenya and Category 2: Malaria in sub-Saharan Africa.

- **Mechanism of Support:** Cooperative Agreement

- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire 5-year project period is $12 million. The number of awards will be up to 4 awards. Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications. Because the nature and scope of the proposed research will vary from application to application, the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration, and cost of the applications received.

- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first budget period, 09/30/2022 to 09/29/2023 will be the following:
    - **Category 1 (Schistosomiasis and/or Soil-Transmitted Helminths in Kenya) –** $500,000 per award
    - **Category 2 (Malaria in Sub-Saharan Africa)** - $700,000 per award

The estimated total funding (direct and indirect) for the entire project period (5 years) will be $12 million. The 5-year project period total funding estimate is:

- **Category 1 (Schistosomiasis and/or Soil-Transmitted Helminths in Kenya) –** $2.5 million per award
- **Category 2 (Malaria in Sub-Saharan Africa)** - $3.5 million per award

The project period is anticipated to run from 09/30/2022 – 9/29/2027.

- **Application Research Strategy Length:** Section IV. "Application and Submission Information" of this announcement clearly specifies page limits for the Research Strategy.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III of this announcement are eligible to apply.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. 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.

- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed.

- **Application Type.** New

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

- **Special Date(s):**

Letter of Intent Due Date: February 1st, 2022.
Application Due Date: March 1st, 2022
Applicants must submit their questions by e-mail to cgherpo@cdc.gov within 3 calendar weeks after the publication date of this NOFO in grants.gov. Questions received after this time will not be considered for response. All changes and updates, including the Q/A, will be added as an amendment to the NOFO and will be posted on www.grants.gov within a reasonable time.

Section I. Funding Opportunity Description

Statutory Authority
Section 301(a) of the Public Health Service Act [42 USC § 241(a)], as amended and Section 307 of the Public Health Service Act [42 USC §242l], as amended, as well as the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, 2020 P.L. 116-136

1. Background and Purpose

The mission of the CDC Center for Global Health, Division of Parasitic Diseases and Malaria (CDC/CGH/DPDM) is to protect and improve the health of Americans and the global community from parasitic disease threats through evidence based public health action. Parasitic infections cause a tremendous burden of disease in both the tropics and subtropics as well as in more temperate climates. Of all parasitic diseases, malaria causes the most deaths globally, killing more than 400,000 people each year. Neglected Tropical Diseases (NTDs), including

Schistosomiasis and/or Soil-Transmitted Helminths, affect more than 1.75 billion people worldwide, largely in rural areas of low- and middle-income countries (LMICs). These diseases exert a large toll on endemic populations, including lost ability to attend school or work, stunting of growth in children, impairment of cognitive skills and development in young children, and a serious economic burden on entire countries. DPDM works with domestic and international partners to prevent and control parasitic diseases by co-implementing the President's Malaria Initiative. DPDM provides essential entomologic, diagnostic, and clinical assistance, and conducting vital research and program evaluation.
This 2-category research NOFO will focus on distinct parasitic diseases that negatively impact the health and wellbeing of communities around the globe: Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya, and Category 2. Malaria in Sub-Saharan Africa. Through this NOFO, DPDM seeks to fund critical research and evaluation activities with the potential to yield high impact public health findings and to improve strategies that will decrease the overall burden of parasitic diseases and increase the health and wellbeing of affected populations. Successful applications will have well developed, research workplans that clearly show short, intermediate, and long-term objectives with a focus on how to identify and track morbidity, develop and test better diagnostic tools, improve surveillance, and develop and evaluate interventions, with the goal of reducing or interrupting transmission of parasitic diseases, including through reduction of their vectors.

CATEGORY 1: SCHISTOSOMIASIS AND/OR SOIL-TRANSMITTED HELMINTHS IN KENYA

Schistosomiasis is a disease caused by parasitic worms that infect more than 200 million people worldwide every year. A high proportion of infections occur in LMICs. When infected people urinate or defecate in fresh water used by communities, it becomes contaminated with *Schistosoma* spp. eggs. The schistosome eggs hatch upon contact with fresh water and release a larval form that infects appropriate intermediate host snails. After an incubation period during which asexual reproduction occurs, infectious larvae are released in water and penetrate the skin of persons in contact with the contaminated water. Worms mature and live in the blood vessels of the human host. The female parasite produces eggs that travel to the bladder and intestine and are passed back into the environment through urine or stool.

Soil-transmitted helminths (STH) are a group of worms that include hookworms (*Necator* and *Ancylostoma* spp.), roundworms (*Ascaris lumbricoides*), and whipworms (*Trichuris trichiura*) that live in the intestines of human hosts and pass eggs into the environment via feces. Over 1.5 billion people in the world suffer from STH infections, with children most heavily affected by malnutrition, anemia, and cognitive impairment. Heavy roundworm infections in some children may cause intestinal blockage or rectal prolapse. Roundworms and whipworms are transmitted when feces contaminate food (sometimes through the use of night soil) and eggs are ingested. Hookworm is transmitted when larval forms of the parasite that have hatched from the eggs penetrate the skin, usually through bare feet.

Control programs for both schistosomiasis and STH are based on mass drug administration (MDA) of therapies that kill adult worms. MDA has been useful in reducing infection levels in many areas. However, MDA alone is unlikely to interrupt transmission of these diseases. Other control measures such as provision of water, sanitation, and hygiene (WASH) are needed.

Furthermore, the diagnostic tools for these infections can have low sensitivity in persons with light infections and are currently too expensive to use for routine annual monitoring and evaluation. The critical infection levels associated with morbidity are also poorly understood for these diseases and evidence-based targets for control are lacking.

An applicant applying for Category 1 should develop a proposal about Schistosomiasis **and/or** Soil-Transmitted Helminths, and designate which specie(s) they intend to focus on. Species to designate are the following: Schistosomiasis - *Schistosoma mansoni* and *Schistosoma haematobium*; Soil-Transmitted Helminths - hookworms (*Necator* and *Ancylostoma* spp.), roundworms (*Ascaris lumbricoides*), and whipworms (*Trichuris trichiura*).

Category 1 applicants should focus their Year 1 activities on the key goals (#1 and/or #2) **in bold** below.
The key goals for Category 1 are:

1. **Determine the factors associated with schistosomiasis and STH morbidity. For example, what is the prevalence level of these infections below which disease is no longer observed in the community? Develop and evaluate improved methods to monitor morbidity (Focus for Year 1).**
2. **Determine WASH levels associated with increased impact of MDA. Validate a WASH assessment tool that can identify community targets to help reduce prevalence (Focus for Year 1).**
3. Evaluate and validate new methods for diagnosis of schistosomiasis and STH that are cost effective to use in monitoring and evaluating control programs.
4. Determine the frequency and geographic level of surveillance that provide reliable data to drive control program decisions as well as rapidly identify hotspots of infection.
5. Identify interventions beyond MDA (e.g., snail monitoring and control for schistosomiasis) that can be employed to increase programmatic success.
6. As new treatments or new formulations of existing treatments become available for schistosomiasis and soil transmitted helminths, evaluate dose, efficacy, impact, required frequency, and any side effects.
7. Improve routine surveillance platforms and ensure that they are collecting high-quality, actionable data, and work with the Ministry of Health to improve utilization of these data.

CATEGORY 2: MALARIA IN SUB-SAHARAN AFRICA
CDC supports the Global Malaria Programme of the World Health Organization and the Roll Back Malaria (RBM) Partnership to coordinate global malaria scale-up and evaluation efforts under the frameworks of the Global Technical Strategy (GTS) for Malaria, 2016—2030. As a partner, CDC has been building and working with numerous international networks, consortia, and partnerships to achieve the GTS targets. The intent of this cooperative agreement is to expand CDC's network of collaborating institutes for both research and technical assistance to targeted malaria-endemic countries in sub-Saharan Africa. Activities funded through this mechanism will focus on research synthesis and malaria operational research aimed at controlling and ultimately eliminating malaria.

An applicant applying for Category 2 should focus their Year 1 activities on the key goals (#1 and/or #2) **in bold**.
The key goals for Category 2 are:

1. **In coordination with global partners, evaluate community-level case management activities and practices for severe and uncomplicated malaria to strengthen the ability of health facilities and community intervention efforts to provide timely and appropriate care and treatment to vulnerable populations (Focus for Year 1).**
2. **Evaluate surveillance as a core intervention (Focus for Year 1).**
3. Evaluate novel prevention strategies, such as malaria vaccines, for efficacy and feasibility, and understand how to optimally implement these strategies.
4. Evaluate the impact of drug-based strategies – including, but not limited to, intermittent mass test and treat, reactive case detection and treatment, and mass drug administration - on malaria morbidity, mortality, and transmission in a targeted geographic area, transmission focus, or segment of a population.
5. Evaluate the continued effectiveness of intermittent preventive treatment during pregnancy and alternative strategies and approaches for prevention of malaria in pregnancy.
6. Evaluate the efficacy of novel vector control tools and technologies such as insecticide treated materials, including use of combination insecticide-treated bed nets, insecticide-treated wall liners, spatial repellents, attractive targeted sugar baits.
7. Monitor the efficacy of first- and second-line antimalarial drugs.
8. Disseminate results from these operational research and prevention activities through written publications, oral presentations, hosting of study tours, or by other means.
9. Assist Ministries of Health in translating operational research findings into public health policy and practice in sub-Saharan Africa, and ensure sharing of expertise and research findings with other partners and countries.

Healthy People 2030 and other National Strategic Priorities
This program addresses "Healthy People 2030" focus areas(s) of Global Health (https://health.gov/healthypeople/objectives-and-data/browse-objectives/global-health) with emphasis on improving global capacity to prevent, detect and respond to public health threats. The project aims to contribute through the rapid identification and control of emerging infectious disease which helps: (1) increase the number of individuals trained globally to prevent, detect, or respond to public health threats (GH-D01); (2) increase the number of globally important public health events that are tracked and reported (GH-D02); (3) increase laboratory diagnostic testing capacity, surveillance, and reporting globally (GH-D03).

Public Health Impact
The public health impact of this proposed work will be two-fold. First, these evaluations and studies will provide critical scientific knowledge to inform and guide program implementation in countries where malaria, schistosomiasis, and soil transmitted helminths are endemic. Secondly, these activities will ultimately help to reduce morbidity and mortality due to malaria, schistosomiasis, and soil transmitted helminths through the identification and scale-up of evidence-based intervention strategies and on-going evaluations of these strategies.

Relevant Work

This NOFO builds on CDC's Division of Parasitic Diseases and Malaria's (DPDM) strategic priorities to work with domestic and global partners "to eliminate the global burden of malaria and neglected tropical diseases." A critical focus of the division is to expand scientific leadership and technical support to accelerate the eradication and elimination of malaria and targeted neglected tropical diseases, and to strengthen the global capacity to control parasitic infections worldwide.

CATEGORY 1: SCHISTOSOMIASIS AND/OR SOIL-TRANSMITTED HELMINTHS IN KENYA

CDC has been collaborating with researchers in Kenya for over 25 years to better understand schistosomiasis. Advances during this time include:

- A better understanding of how co-infections with HIV or malaria affect schistosomiasis and how schistosomiasis affects these infections
- Investigation of differences in persons who rapidly become reinfected compared to those who appear more resistant
- Evaluation of circulating antigen-based diagnostic tools
- Discovery, and description of geographic hotspots of infection
- Evaluation of different MDA schedules for reducing prevalence and morbidity in communities with moderate or high baseline prevalence, and
- Introduction of new methods for ultrasound evaluation of intestinal morbidity that make this diagnostic tool more accessible to control programs.

DPDM's work on soil-transmitted helminths is much less extensive and focused primarily on risk factors for their transmission in urban informal settlements

CATEGORY 2: MALARIA IN SUB-SAHARAN AFRICA

For more than 75 years, CDC has been a leader in the fight against malaria since its successful elimination in the United States. Building on that success, CDC experts continue to develop and evaluate malaria control interventions to reduce malaria illness and death with the ultimate goal of global elimination. CDC's strategic research helped develop and evaluate critical tools that are now used throughout the world to prevent and control malaria, including:

- Insecticide-treated bed nets (ITNs)
- Intermittent preventive treatment for pregnant women (IPTp) and infants (IPTi)
- Improved management of malaria illness with rapid diagnostic tests (RDTs) and artemisinin-containing combination therapies (ACTs)
- Indoor residual spraying (IRS)

CDC continues to pursue the strategic goal of reducing the global burden of malaria. Despite the scale up of proven strategies, the pace of malaria reduction has slowed in recent years. More research is needed to identify the optimal combinations of interventions and how best to implement them to drive down transmission. Additionally, CDC seeks to:

- Identify the optimal means of scaling up case management,
- Assess the utility of drug-based prevention strategies,

- Understand how and where to best implement malaria vaccines,
- Identify novel vector control methods to control malaria more effectively, and
- Develop health facility and routine community surveillance platforms and assess how these can be used in decision making. The goal is for these platforms to eventually reduce or eliminate the need for costly ad hoc surveys to monitor the impact of interventions on malaria burden and transmission.

2. Approach

Collaborative public health research will provide critical information on ways to monitor, control, and potentially eliminate parasitic diseases including malaria, schistosomiasis, and soil-transmitted helminths.

Approaches for Category 1. Schistosomiasis and/or Soil-Transmitted Helminths include the following. The applicant is expected to select a subset of these approaches to address in their application to meet the year 1 priority goals (stated in 1. Background and Purpose - Section 1. Funding Opportunity Description - Part 2. Full Text):

1. Conduct operational research, monitoring, and evaluation of Schistosomiasis and/or Soil-Transmitted Helminths activities to assess the efficacy/ effectiveness of NTD control tools, including diagnosis and improvement of routinely collected surveillance data.
2. Evaluate and measure the effectiveness and impact of control interventions for Schistosomiasis and/or Soil-Transmitted Helminths including mass drug administration (MDA), intermediate host control approaches, sanitation, and other methods of transmission reduction.
3. Explore approaches to measure the force of transmission and evaluate its importance in prevalence and intensities of Schistosomiasis and/or Soil-Transmitted Helminths infections.
4. Evaluate new diagnostic tools for Schistosomiasis and/or Soil-Transmitted Helminths.
5. Evaluate surveillance approaches for Schistosomiasis and/or Soil-Transmitted Helminths to identify the best frequency and granularity of surveys that will inform control programs in a cost-effective manner.
6. Build epidemiological, entomological, laboratory, health economics, and social science capacity for NTD investigations.

Approaches for Category 2. Malaria includes the following. Applicants are expected to select a subset of these approaches to address in their application. However, approaches 1 and 2 should be a focus for year 1:

1. Evaluate community-level case management activities and practices for severe and uncomplicated malaria (focus for year 1).
2. Evaluate surveillance as a core intervention (focus for year 1).
3. Conduct malaria epidemiological surveillance for infection, morbidity, and mortality.
4. Conduct entomological surveillance, including but not limited to insecticide resistance, vector composition and behavior of malaria and arboviral diseases. Elucidate the mechanisms of insecticide resistance, measure the impact of insecticide resistance on the efficacy of current interventions and develop/ evaluate new tools to mitigate the impact of insecticide resistance.
5. Conduct research on the development or assessment of new tools, including new vaccines and new vector control tools and technologies.

6. Conduct clinical research aimed at reducing morbidity and mortality in the vulnerable populations of children below 5 years of age and pregnant women.
7. Monitor or measure use, coverage, efficacy, and effectiveness of known and newly proven interventions (ITNs, IPTp, IRS, CM, malaria vaccine). This includes monitoring antimalarial drug efficacy/resistance both in vivo and in vitro.
8. Conduct operational research, including but not limited to social-cultural research, aimed at improving uptake of known/proven malaria control strategies.
9. Leverage resources to support research and infrastructure (e.g., enhanced data systems for real-time access to data, physical space) to accelerate progress towards malaria elimination in sub-Saharan African countries, including testing new tools/interventions to further reduce malaria transmission with the ultimate goal of malaria elimination.
10. Provide technical support to Malaria Control Units within Ministries of Health, and support translation of research to policy/practice.

Objectives/Outcomes
Objectives specific to each category are stated below and applicants may propose a variety of projects that address these objectives.

CATEGORY 1. SCHISTOSOMIASIS AND/OR SOIL-TRANSMITTED HELMINTHS

- Better understanding of community factors associated with schistosomiasis and STH morbidity, including ways to measure or predict where morbidity will occur.
- Improved methods for measuring WASH at the community level and investigating what WASH measures are associated with more effective MDA.
- Improved field- and laboratory-based diagnostic tools that provide community-level monitoring and evaluation.
- Cost-effective sampling schemes that provide timely information to control programs so that adjustments to intervention approaches can be implemented.
- Validated interventions beyond MDA and WASH that are effective at reducing NTD prevalence.

CATEGORY 2. MALARIA

- Improved understanding of the efficacy of currently deployed malaria control interventions in sub-Saharan Africa, especially those interventions threatened by insecticide-resistant vectors and drug-resistant parasites.
- Additional data on innovative interventions that address key challenges in vector control including interventions that address:
    - Insecticide resistance and outdoor transmission
    - Improving malaria case management at health facility and community levels
    - Accessing hard-to-reach populations
    - Reducing transmission through targeting the parasite reservoir, and
    - Developing new tools to improve surveillance, monitoring, and evaluation.
- Improved translation of operational research findings into better public health practice globally.

- Enhanced information about the feasibility and impact of transforming surveillance into a key malaria intervention.
- Identification and assessment of improved and cost-effective approaches to monitoring changes in malaria burden.
- Expanded capacity of Ministries of Health to conduct operational research, surveillance, and monitoring and evaluation of malaria control activities.

Target Population
The target population includes persons at risk for schistosomiasis, soil-transmitted helminths, and malaria in affected countries throughout the world. Sub-population target groups within malaria transmission zones should include those most at-risk e.g., children under five years of age and pregnant women.

Collaboration/Partnerships
Applications are required to include a letter of support from Health Ministries in countries in which they propose to work to verify previous and ongoing collaborations. Documentation of any Memoranda of Understanding/Memoranda of Agreement (MOU/MOA) should also be included in the appendix to the application.
Successful applicants will be expected to collaborate closely and have regular communication with their governmental Health Ministries, in addition to the CDC country offices, CDC in-country point of contacts, and other CDC-funded partners where applicable.

Please see Section III.5 - Eligibility Information, Responsiveness.

Evaluation/Performance Measurement
The application should include measurable goals and aims based on a 5-year research project period. The grantee 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.

Evaluations/performance measures will be established by specific program areas dependent upon the category for which the awardee is funded.

Translation Plan
Applicant should describe plans for how research and scientific findings will be reported and disseminated (e.g., peer-reviewed journals, scientific presentations, reports, meetings, and conferences) and specify how these activities are integrated into the project plan. The translation of findings 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.
Questions to consider in preparing this section include:

- How will the scientific findings inform the public health policy or practices of local governments and other stakeholders?
- How will the project improve or affect the translation of study findings into policy or practice?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs and practices?
- How will the findings advance or guide future scientific efforts or related activities?
- How will the research improve health outcomes?

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (Cooperative Agreement)
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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

Estimated Total Funding:
$12,000,000
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $5 million
Category 2. Malaria in sub-Saharan Africa: $7 million

Estimated Total Annual Budget Period Funding:

Year 1: $2.4M
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M
Category 2. Malaria in sub-Saharan Africa: $1,400,000
Year 2: $2.4M
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M
Category 2. Malaria in sub-Saharan Africa: $1,400,000
Year 3: $2.4M
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M
Category 2. Malaria in sub-Saharan Africa: $1,400,000
Year 4: $2.4M
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M
Category 2. Malaria in sub-Saharan Africa: $1,4700,000

Year 5: $2.4M
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M

Category 2. Malaria in sub-Saharan Africa: $1,400,000
***Estimated total funding available for first year (first 12 months), including direct and indirect costs: $2.4M**
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $1M
Category 2. Malaria in sub-Saharan Africa: $1,400,000
***Estimated total funding available for entire project period, including direct and indirect costs: $12 million**
Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya: $5 million
Category 2. Malaria in sub-Saharan Africa: $7 million

Anticipated Number of Awards:
4
Awards issued under this NOFO are contingent upon 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:
$2,400,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

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

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

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

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)

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.

2. Foreign Organizations

Foreign Organizations **are** eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm DUNS by sending an e-mail to ccrhelp@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/AC135Public/Docs/US%20Instructions%2 0for%2 0NSPA%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.

3. Additional Information on Eligibility

N/A

4. Justification for Less than Maximum Competition

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.nspa.nato.int/AC135Public/Docs/US%20Instructions%2 0for%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/#1.
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 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 registration process at least four (4) weeks prior to the application due date.

5. Responsiveness

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

1. Applicants may not exceed the budget limit specified for Year 1 of the respective category to which they are applying. Applicants may not apply for more than $500,000 for Category 1 and $700,000 for Category 2 for Year 1. If an applicant requests a funding amount greater than the ceiling as indicated in Section II. of this NOFO, CDC will consider the application non-responsive, and the application will not enter the review process. CDC will notify the applicant that the application did not meet the submission requirements.
2. This is a 2-Category research NOFO – Category 1: Schistosomiasis and/or Soil-Transmitted Helminths in Kenya, and Category 2: Malaria in Sub-Saharan Africa. Only one application per institution (normally identified by having a unique DUNS number) is allowed, and each applicant can only apply for 1 category. If an applicant applies to both categories, their applications will be considered non-responsive and will not move forward for review and consideration for funding.

3. Applications must include a documented letter of support, as well as provide documentation of any MOU/MOA, from Health Ministries in countries in which they propose to work, to verify previous and ongoing collaborations.

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.

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf

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

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

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

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

All applicant organizations **must obtain** a 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 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.

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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 SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its 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 NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

Only one application per institution (normally identified by having a unique DUNS number) is allowed for each Category. Additionally, the same organization can not apply for both Category 1 AND Category 2. If they do, neither application will move forward for review nor receive funding. PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS.

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), applications received in response to the same funding opportunity announcement 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.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

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

Please use the form and instructions for SF424 (R&R) Form G. Applicants must use FORMS-G application packages for due dates on or after January 25, 2022.

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 Subaward Budget Attachment(s) Form 5 YR 30 ATT.

* [Add any additional instructions to applicants regarding the form and content of the application in this free form text box. E.g., any instructions on what should be placed in the additional attachments section, etc.]

3. Letter of Intent

Due Date for Letter Of Intent 02/01/2022

02/01/2022
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. “Overview Information”, prospective applicants are encouraged 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

Send the letter of intent to:
Sheila Okoth, PhD.,
Scientific Program Official,
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 30329.
Email: JYO3@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

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

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

Please use the form and instructions for SF424 (R&R) Form G. Applicants must use FORMS-G application packages for due dates on or after January 25, 2022.

6. Appendix

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

Do not use the appendix to circumvent page limits. A maximum of 20 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 20 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

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

Applicants must use FORMS-G application packages for due dates on or after April 4, 2022 and must use FORMS-F application packages until April 3, 2022.

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

Please use the form and instructions for SF424 (R&R) Form G. Applicants must use FORMS-G application packages for due dates on or after January 25, 2022.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have

time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

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

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

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

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

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

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
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 03/01/2022

03/01/2022
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the 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/additional-requirements/ar-25.html

Human Subjects:

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

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

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

Applying institutions must be eligible to receive funding that originates with the United States Agency for International Development (USAID).

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) Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.

3) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

4) 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

applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements.

Non-compliance with this Policy may result in suspension, limitation, or termination of USG 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.

5) 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.

11. 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. 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_ redirect.htm? id=11144).

Important reminders:

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

It is also important to note that for multi-project applications, this requirement also

applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the 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.

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

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

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

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

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), 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?

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?

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?

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?

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?

2. Additional Review Criteria

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

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

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

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/VAChecklist.pdf).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations

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

Resource Sharing Plan(s)

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/additional-requirements/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.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

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

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/interestedinapplying/application-resources.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.

Funding Preferences

For Category 1: Schistosomiasis and/or Soil-Transmitted Helminths in Kenya, applicants should provide evidence of working with the national deworming program and plans to engage with national control efforts as part of the proposed work.
For Category 2: Malaria in sub-Saharan Africa, applicants should provide evidence of working with the national and regional malaria control program and plans to engage with national control efforts as part of the proposed work. No more than one 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 with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (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 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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 (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. In preparation for the federal government's April 4, 2022, transition from the Data Universal Numbering System (DUNS) to the Unique Entity Identifier (UEI), applicants must obtain a UEI. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the 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: https://www.archives.gov/

Specific requirements that apply to this NOFO are the following:

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 – ATSDR
AR-18: Cost Recovery – ATSDR
AR-19: Third Party Agreements – 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, "Federal Leadership on Reducing Text Messaging while Driving", 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 – 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

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.
To view brief descriptions of relevant CDC requirements visit: http:// www.cdc.gov/ od/OGS/funding/ grants/additional_ req.shtm.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

• For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: 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 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/additional-requirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

4. Cooperative Agreement Terms and Conditions

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

NOTE: The Office of Management and Budget (OMB) requires that all projects in which CDC

staff will provide technical assistance or advice on any information collections on 10 or more people that are planned or conducted by the awardee, all such information collections – where CDC staff will be or are approving, directing, conducting, managing, or owning data – must undergo OMB project determinations by CDC and might require OMB PRA clearance prior to the start of the project.

Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance: Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals. See https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious freedom/index.html

The following responsibilities apply to applicants, and CDC, for both Component 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya and Component 2. Malaria in sub-Saharan Africa:

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the

appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.

- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- Engage with local Health Ministries to keep them informed of ongoing cooperative agreement activities
- 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 grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Agreeing to share data, specimens and other project and programmatic information with CDC scientists, as well as appropriate international partners, such as the local Ministry of Health and World Health Organization upon request.
- Working with HHS/CDC scientists to refine protocols to improve the study and other proposal components based on reviewers' comments in the summary statement.
- Participating in conferences with HHS/CDC project official(s) and research team; and attending in-person meetings with HHS/CDC co-investigators.
- 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 CDC and the engaged IRBs for review and approval. You must have CDC and IRB approval before the protocol and any amendments are implemented.
- Where applicable, engage with other CDC-funded partners as identified by DPDM.

***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
- Monitoring the cooperative agreement and provide input on its implementation.
- Collaborating with the awardee 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.
- Monitoring and evaluating scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses.
- Providing technical assistance to the recipient and linking them with other national and international agencies that might provide additional technical or material assistance.
- Collaborating with the affiliated institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
- If appropriate, Epidemic Intelligence Officer(s) and CDC staff will accompany the awardee with field investigation.
- Providing technical assistance or advice on any data collections on 10 or more people that are planned or conducted by the awardee. All such data 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.

Areas of Joint Responsibility include:
None; all responsibilities are divided between awardees and CDC staff as described above.

None; For both Category 1. Schistosomiasis and/or Soil-Transmitted Helminths in Kenya and Component 2. Malaria in Sub-Saharan Africa, all responsibilities are divided between awardees and CDC staff as described above.

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

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

5. Reporting

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

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

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

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

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

A. Submission of Reports

The Recipient Organization must 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/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.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) 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.**
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 (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

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

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

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

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?

- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

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

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

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

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

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

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

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants

should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the 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 is 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_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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.

6. Termination

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

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

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

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

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

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

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

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

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

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

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

3) Terms: For purposes of this clause:

"Commodity" means any material, article, supplies, goods, or equipment;

"Foreign government" includes any foreign government entity;

"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

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

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

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

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
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)

Category 1. Schistosomiasis and/or Soil-Transmitted Helminths
W. Evan Secor
Center for Global Health (CGH), Division of Parasitic Diseases and Malaria
Telephone: 404-718-4141
Email: WAS4@cdc.gov

Category 2. Malaria
Julie Gutman
Center for Global Health (CGH), Division of Parasitic Diseases and Malaria
Telephone: 404-718-4730

Email: FFF2@cdc.gov

Peer Review Contact(s)
Lata Kumar
Center for Global Health (CGH), Office of Director
Telephone: 404-639-7618
Email: lek7@cdc.gov

Financial/Grants Management Contact(s)
Angie Willard
Office of Financial Resources (OFR)/ Office of Grants Services
Telephone: 770-488-2863
Email: aen4@cdc.gov

Section VIII. Other Information

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

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

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

Public Health Service Act,Section 301(a) of the Public Health Service Act [42 USC § 241(a)], as amended and Section 307 of the Public Health Service Act [42 USC §242l], as amended, as well as the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, 2020 P.L. 116-136

Q&A

1. Q. - I would like to know if International Non-Profit organization is eligible for it or not. We would like to apply for it and prepare our proposals.
    a. *International non-profit organizations are eligible to apply to this Notice of Funding Opportunity as stated in 'Part 1. Eligible Applicants' of 'Section III. Eligibility Information'. This section states, in part that "…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."*

2. Q. - Are start-up organizations eligible for the funding opportunity?

a. *Start-up organizations are eligible to apply for this funding opportunity as indicated 'Part 1. Eligible Applicants' of 'Section III. Eligibility Information'.*

3. Q. - Page 23 states that 10 pdf documents are allowed to be included in the appendix, however page 24 states that 20 pdf documents are allowed to be included in the appendix. Can the CDC please clarify which is the correct limit?
    a. *The maximum number of pdf documents allowed for this Notice of Funding Opportunity is ten (10). The amended NOFO will be corrected to clarify the 10-pdf document limit in 'Part 6. Appendix' under 'Section IV. Application and Submission Information'.*
4. Q. - Can CDC clarify the geographical scope they would like to see included in the workplan? (Multi-national vs National vs District vs Health zones)
    a. *Category 1 - Schistosomiasis and STH: This work should focus on District and Health Zone levels.*
    b. *Category 2 - Malaria: We are happy to receive projects from partners able to work in multiple countries. Based on expected budgets, we would expect projects at District and Health Zone levels.*
5. Q. - Can CDC please clarify whether there is preference between evaluation across a country versus evaluation in a specific setting and district.
    a. *Category 1 - Schistosomiasis and STH: This work should focus on district rather than national levels.*
    b. *Malaria: We do not have a preference for national vs district level.*
6. Q. - Are clinical trials allowed within this mechanism?
    a. *Category 1 - Schistosomiasis and STH: Yes, provided the same stipulations as described for Category 2 - Malaria.*
    b. *Category 2 - Malaria: Yes, clinical trials are allowed provided that they can be completed within the allocated timeframe and budget, and noting that funds will be allocated on a yearly basis with no guarantee of funding in subsequent years.*
7. Q. - Is implementation included within this mechanism, or will the consortium only be evaluating existing interventions?
    a. *Category 1 - Schistosomiasis and STH: Implementation alone (i.e., program delivery) does not address this research funding opportunity, but development and evaluation of implementation approaches (i.e., identifying optimal delivery methods) addresses the funding opportunity goals.*
    b. *Category 2 - Malaria: Depending on the question to be assessed, the partner may include implementation.*

8. Q. - Will CDC consider evaluation of innovative approaches to intervention deployment processes and M&E?
    a. *Category 1 - Schistosomiasis and STH: Innovative approaches are welcomed.*
    b. *Category 2 - Malaria: Yes, we will certainly consider innovative approaches to deploy interventions and M&E.*

9. Q. - Will the incumbent be allowed to access CDC-handled distribution channels for the RTS,S vaccine and other commodities?
    a. *Category 1 - Schistosomiasis and STH: N/A*
    b. *Category 2 - Malaria: CDC does not have distribution channels for the RTS,S vaccine or other commodities. CDC would facilitate working with in country and ministry partners and channels to the extent possible.*

10. Q. - Can CDC please confirm if there is a maximum indirect cost rate for Categories 1 and 2?
    a. *For foreign organizations and entities, please see the subsection 'Budget and Period of Support' which states "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."*

In 'Section V. Application Review Information' under 'Part 3. Additional Review Considerations' this Notice of Funding Opportunity states that potential applicants must include a copy of either a current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter.

11. Q. - If an organization does not have a Negotiated Indirect Cost Rate Agreement (NICRA), is documentation of prior financial audits acceptable justification for a proposed indirect cost rate? If not, what additional documentation is sufficient justification?
    a. *In Section V 'Application Review Information' under 'Part 3 Additional Review Considerations' this Notice of Funding Opportunity states that potential applicants must include a copy of either a current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter.*

12. Q. - In reading this RFA, it seems to only address malaria work in Sub-Saharan Africa (SSA). Can you confirm that this RFA will NOT fund malaria projects in regions outside of SSA?

a. *The focus of the Notice of Funding Opportunity in terms of region and countries is described in 'Section I. Funding Opportunity Description' under 'Part 1. Background and Purpose'. Category 1 of this NOFO addresses Schistosomiasis and/or Soil-transmitted Helminth work in Kenya, while Category 2 addresses Malaria in Sub-Saharan Africa.*

13. Q. - Applicants are expected to select a subset of approaches listed to address in the application, and that Approaches 1 (Evaluate community-level case management activities and practices for severe and complicated malaria) and 2 (evaluate surveillance as a core intervention) should be a focus for year 1. My question: must the project address BOTH or is it enough with ONE of them?
    a. *This Notice of Funding Opportunity lists the key goals for each respective Category (1 and 2) on which prospective applicants should focus their proposed activities in 'Section I. Funding Opportunity Description' of 'Part 1. Background and Purpose'. Prospective applicants may focus their proposed activities to address one of the Approaches.*

The amended NOFO will be modified to make two corrections in 'Section 1. Funding Opportunity Description', as indicated below:

- *In 'Part 1. Background and Purpose' under 'Category 2: Malaria in Sub-Saharan Africa' [page **7 of 52**], Key Goal #1 will be corrected to read as follows: "In coordination with global partners, evaluate community-level case management activities and practices for severe and **un**complicated malaria to strengthen the ability of health facilities and community intervention efforts to provide timely and appropriate care and treatment to vulnerable populations (Focus for Year 1).*
- *In 'Part 2. Approach' under 'Approaches for Category 2. Malaria', Approach #1 [page **10 of 52**], will be corrected to read as follows: "Evaluate community-level case management activities and practices for severe and **un**complicated malaria (focus for year 1)."*

14. Q - Will proposals addressing BOTH Approach1 and Approach 2 be more strong for the independent panel? It is not fully clear to me if the number of approaches covered by the project is an element that will be taken into account in the evaluation.

- *This NOFO will be amended in Section I: Background and purpose to specify that applicants can develop their proposals to focus on key goal 1 AND/OR key goal 2, as follows:*
    - *[Page **6 of 52**]: "An applicant applying for Category 1 should focus their Year 1 activities on the key goals (#1 **and/or** #2)"*
    - *[Page **7 of 52**]: "An applicant applying for Category 2 should focus their Year 1 activities on the key goals (#1 **and/or** #2)*

15. Q. - The Letter of Intent is due for submission on 1 Feb. (section 3 on page 21) of the NOFO?

'*Part 3. Letter of Intent' in 'Section IV. Application and Submission Information' of this NOFO states that the due date for the Letter of Intent is February 1st, 2022. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.*

a. We do not need to submit the forms on 1 Feb, only the letter of intent?

Only the Letter of Intent is due on February 1st, 2022.

b. If encouraged to apply for the full proposal, then we follow the steps in 'Section 2: Content and Form of Application Submission' with the list of mandatory forms and one optional form. *Potential applicants are encouraged to apply for this Notice of Funding Opportunity regardless of submitting a Letter of Intent. Please follow instructions in the application package and use mandated forms as well as optional forms, if needed.*

c. Is there a word limit for the letter of intent? *There is no word limit. 'Part 3. Letter of Intent' in 'Section IV. Application and Submission Information' of this NOFO outlines the information requested in the Letter of Intent.*