

Centers for Disease Control and Prevention

Center for Global Health Extramural Research Program Office

Institutional Research Collaboration between the Liverpool School of Tropical Medicine and the Centers for Disease Control and Prevention

RFA-GH-15-0060102SUPP16

Application Due Date: 02/23/2016

Institutional Research Collaboration between the Liverpool School of Tropical Medicine and the Centers for Disease Control and Prevention

RFA-GH-15-0060102SUPP16

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GH15-006-SUPP-16
Institutional Research Collaboration between the Liverpool School of Tropical Medicine and the Centers for Disease Control and Prevention
ANNOUNCEMENT PUBLICATION | VALIDATE & APPROVE

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Center for Global Health Extramural Research Program Office (CGH ERPO)
Center for Global Health (CGH)

Funding Opportunity Announcement (FOA) Title

Institutional Research Collaboration between the Liverpool School of Tropical Medicine and the Centers for Disease Control and Prevention

Activity Code

Non-competing program expansion supplement

Funding Opportunity Announcement Type

Reissue of RFA-GH-15-006

Funding Opportunity Announcement Number

RFA-GH-15-0060102SUPP16

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.326

Category of Funding Activity:

Health

FOA Purpose

The purpose of this cooperative agreement is to assist with the development of operational research, surveillance, and monitoring and evaluation activities in sub-Saharan Africa and Asia. Through this funding announcement, the Malaria Branch seeks to fund innovative research projects and evaluation activities with the potential to yield high impact public health findings or strategies that will decrease the overall burden of malaria and increase the health and well-being of the populations. CDC's Malaria Branch is a partner of the Roll Back Malaria (RBM) initiative, a partnership that seeks to support and coordinate global malaria program scale-up, surveillance, and evaluation efforts in malaria endemic countries.

Key Dates

Publication Date: **To receive notification of any changes to GH15-006-SUPP-16, 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: N/A

N/A

Application Due Date: ***February 23, 2016, FEDEX to CDC OGSTIMS by 5 P.M. EST***

On-time submission requires that applications be error-free and made available to CDC Office of Grants Services(OGS)

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date 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: **03/07/2016**

Secondary Review: **03/14/2016**

Estimated Start Date: **09/01/2015**

Expiration Date: **03/08/2016**

Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 16 pages.

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

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

Executive Summary

- **Purpose.** The purpose of this FOA is to assist with the development of operational research, surveillance, and monitoring and evaluation activities in sub-Saharan Africa and Asia. Through this funding announcement, the Malaria Branch seeks to fund innovative research projects and evaluation activities with the potential to yield high impact public health findings or strategies that will decrease the overall burden of malaria and increase the health and well-being of the populations.
- **Mechanism of Support.** Cooperative agreement
- **Funds Available and Anticipated Number of Awards.** $17,500,000. We anticipate one award under this FOA contingent upon availability of funds.
- **Budget and Project Period.** $3,500,000 for the first year 12 month budget period and the estimated total funding $17,500,000 for the entire project period. The project period will run from 04/06/2016 – 08/31/2020.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. 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.** State the authoritative structure you expect to see in submitted applications.
- **Number of Applications.** Eligible applicant institutions may only one application.
- **Application Type.** Supplement

- **Application Materials.** See Section IV.1 for application materials.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

301(a) and 317(k) (2) of the Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b (k) (2), as amended.

1. Background and Purpose

Background

Malaria prevention and control are major foreign assistance objectives of the U.S. Government (USG). In May 2009, President Barack Obama announced the Global Health Initiative (GHI), a six-year, comprehensive effort to reduce the burden of disease and promote healthy communities and families around the world. Through the GHI, the United States will invest $63 billion over six years to help partner countries improve health outcomes, with a particular focus on improving the health of women, newborns and children.

The GHI aims to maximize the impact the United States achieves for every health dollar it invests, in a sustainable way. The GHI's business model is based on: implementing a woman and girl-centered approach; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; encouraging country ownership and investing in country-led plans and health systems; improving metrics, monitoring and evaluation; and promoting research and innovation. The GHI will build on the USG's accomplishments in global health, accelerating progress in health delivery and investing in a more lasting and shared approach through the strengthening of health systems.

The President's Malaria Initiative (PMI) is a core component of the GHI, along with HIV/AIDS and tuberculosis. As part of the USG Malaria Strategy 2009-2014 [PDF, 483KB], an expanded PMI strategy has been developed to achieve Africa-wide impact by halving the burden of malaria in 70 percent of at-risk populations in sub-Saharan Africa, approximately 450 million people, thereby removing malaria as a major public health problem and promoting economic growth and development throughout the region. Since its launch in 2005, PMI has reinforced the principles that are part of GHI, including: encouraging country ownership and investing in country-led plans and health systems; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; implementing a woman- and girl-centered approach; improving monitoring and evaluation; and promoting research and innovation.

Purpose

The purpose of this cooperative agreement is to 1) conduct operations research in malaria in sub- Saharan Africa and Asia, 2) support the establishment of monitoring and evaluation systems for malaria program activities, including those supported by the PMI and 3) establish feasible and effective opportunities for integration with other child survival, vector control and infectious disease programs. This Funding Opportunity will support ongoing research and collaboration and additionally support the evaluation of the efficacy and safety of the PfSPZ vaccine.

The following are specific activities for the recipient to address in collaboration with CDC and the Ministries of Health and Population (MoH): a) In coordination with global partners, strengthen the ability of health facilities and community intervention efforts to provide timely and appropriate care and treatment of sick children under 5 years of age by evaluating case management activities and practices, including the use of rapid diagnostic tests and pre-referral rectal artesunate at the community level, b) Promote the

importance of administering the correct anti-malarial drug and correct dosage by drug sellers, pharmacists, and other MoH designated agents in the community, c) Evaluate the use and impact of vector control intervention measures such as insecticide treated materials, including use of combination insecticide-treated bednets, insecticide-treated wall liners, spatial repellents and toxic baited sugar traps; d) Evaluate the impact of strategies such as intermittent mass screen and treat and mass drug administration on malaria transmission; e) Evaluate the continued effectiveness of intermittent preventive treatment during pregnancy and alternative strategies and approaches for prevention of malaria in pregnancy; f) Monitor the efficacy of first- and second-line antimalarial drugs; g) Determine thesafety and efficacy of the PfSPZ Vaccine; h) Disseminate results from these operational research and prevention activities through written publications, oral presentations, hosting study tours, or by other means, and i) Assist the MoH in translating operational research findings into public health practice in sub-Sahara Africa and Asia, and ensure sharing of expertise and research findings with other partners and countries.

Healthy People 2020 and other National Strategic Priorities

The President's Malaria Initiative (PMI) is a core component of the GHI, along with HIV/AIDS and tuberculosis. As part of the USG Malaria Strategy 2009-2014 [PDF, 483KB], an expanded PMI strategy has been developed to achieve Africa-wide impact by halving the burden of malaria in 70 percent of at-risk populations in sub-Saharan Africa, approximately 450 million people, thereby removing malaria as a major public health problem and promoting economic growth and development throughout the region. Since its launch in 2005, PMI has reinforced the principles that are part of GHI, including: encouraging country ownership and investing in country-led plans and health systems; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; implementing a woman- and girl-centered approach; improving monitoring and evaluation; and promoting research and innovation.

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 malaria program implementation in sub-Saharan Africa and Asia. Public health policy (Malaria Control Program) may be changed based on the outcomes from these research findings. The effectiveness of the specific projects being tested in reducing malaria transmission, morbidity, and mortality will be measured. Second, the ultimate impact of these activities will be reduced morbidity and mortality due to malaria through the scale-up of evidence-based intervention strategies and on-going evaluations of these strategies.

Relevant Work

2. Approach

Scientific knowledge to be achieved through research supported by this program includes:

- Evaluation of potentially efficacious vaccines to complement current malaria control measures, and development of new tools to improve surveillance, monitoring and evaluation;
- Ensure that operational research findings are translated into better public health practice globally.

Objectives/Outcomes

- Evaluate the safety, tolerability, and efficacy against *P falciparum* infection during 6 months follow-up of PfSPZ Vaccine administered as 3 doses by DVI at 900,000 PfSPZ per dose or 450,000 PfSPZ per dose, or in 4 doses at 900,000 PfSPZ per dose. The secondary objectives include the evaluation of the immunogenicity of the vaccine and efficacy against infection during 12 months follow-up.

Target Population

Target populations should include people living or working in epidemiological defined areas of malaria transmission in sub-Saharan Africa and Asia. Sub-population target groups within these malaria transmission zones should include those most at-risk e.g. children under five years of age and pregnant women.

Collaboration/Partnerships

Key stakeholders and partnerships include National Malaria Control Programs, the United States Agency for International Development (USAID), PMI implementing partner organizations, the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), and the Global Fund.

Evaluation/Performance Measurement

Monitoring and Evaluation

- Work with CDC and other global partners as appropriate to develop and implement an evaluation plan to measure the impact of the activities outlined in this funding opportunity announcement (evaluation framework, evaluation design, indicators, process and outcome evaluation, and information/data collection plan).

Program Capacity

- Establish or retain a full-time staff person with management and technical experience, responsible for managing the planning, implementation, and evaluation of the program and serving as the CDC point of contact.
- Establish or retain a part-time staff person with data management and mobile data collection experience responsible for the programming and trouble-shooting of data collection instruments, cleaning of data, development of data dictionaries and storage of datasets.
- Establish or retain additional staff with demonstrated knowledge, skills, and expertise in administrative and fiscal management to meet the needs of the program.
- Over the course of the project period establish and retain other staff, contractors, and consultants sufficient in number and expertise to ensure project success.

Fiscal management

- Programs must use funding to support programs in alignment with requirements of this FOA.
- Programs must develop and maintain systems for sound fiscal management, including: monitoring the cooperative agreement award and program contracts and grants, ensuring the funds are expended in support of approved activities; tracking expenditures in a timely manner; and preventing excessive unobligated balances.

Translation Plan

Applicant should use appropriate scientific journals to disseminate research findings to the broader scientific community in conjunction with CDC scientists. Applicant should present important evaluation and research findings at relevant international scientific meetings and conferences.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

Revision (formerly Competing Supplement) - Request for additional funds for a current award to expand the scope of work. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Estimated Total Funding: $17,500,000

Anticipated Number of Awards: 1

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

Award Ceiling: $0 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 5 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

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

Additional Eligibility Category:

Other:

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%20for%20NSPA%20NCAGE.pdf.

Foreign components of U.S. Organizations are not eligible to apply.

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

3. Special Eligibility Requirements

Applicants must demonstrate an ability to organize malaria-focused consortia to conduct malaria epidemiologic and entomologic studies in sub-Saharan Africa and Asia. This should include a proven track record in organizing and managing large groups of diverse research institutions, international public health groups, and Ministries of Health for the purpose of identifying the malaria research agenda and implementing research studies across multiple sites and epidemiologic transmission zones. Applicants must demonstrate previous malaria research or public health activities in sub-Saharan Africa and Asia. Applicants should document eligibility through manuscripts showing previous work in these regions or through reference letters from public health officials.

4. Justification for Less than Maximum Competition

The Liverpool School of Tropical Medicine (LSTM) is uniquely qualified for this award based on the following experience and capabilities:

The LSTM is the central coordinating body for several international malaria consortia, there-by making it uniquely suitable to conduct these activities. These include:

Malaria in Pregnancy (MIP) Consortium: This is a global partnership of 42 research institutions worldwide active in malaria control in pregnancy research. LSTM is the coordinating institution and is responsible for the coordination of the research activities of the Consortium, advocates for the topic, hosts the MIP resource centre, and acts as the host of the drug safety database of antimalarials in pregnancy. This is the only centralized database for combining results from several multi-centre trials. Because this is the main international research network in this field, LSTM is the only institution that is in a position to conduct this kind of international research collaboration for operational research of malaria in pregnancy.

The Cochrane Infectious Diseases Group: This is a group that since 1994 has specialized in the field of meta-analysis and has been preparing systematic reviews on the benefits and harms of healthcare interventions for infectious diseases, particularly malaria, tuberculosis, diarrhea, and tropical diseases. The editorial base is located at the LSTM and hence, they are uniquely positioned to conduct the meta-analysis of the malaria focused multi-centre trials proposed in this program.

Innovative Vector Control Consortium (IVCC). This research program is the largest malaria vector control partnership in the world and involves institutions from the US, UK, Asia and Africa. LSTM is the coordinating institution for the IVCC, and hence plays a pivotal role in development and delivery of new products and tools in reducing transmission of vector-borne diseases, effective campaigns to control malaria, and malaria elimination.

In addition LSTM participates with CDC and other partners on several other global research and policy forum: The Antimalarial Combination Therapy Consortium, The WHO Technical Expert Group on

Containment of Antimalarial Drug Resistance, The Roll Back Malaria Partnership (including Malaria in Pregnancy, Vector Control and Case Management Working Groups), and the International Centers of Excellence for Malaria Research.

5. Responsiveness

N/A

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.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.

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.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the grantee 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 grantee organization.

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

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

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 FOA 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.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement 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 forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent:

N/A

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

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 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, 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 FOA. **2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health. **3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline. **4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY) **5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects 7. Inclusion of Women and Minorities 8. Targeted/Planned Enrollment Table (for New Application ONLY) **9. Inclusion of Children**

Other Research Plan Sections

10. Vertebrate Animals 11. Select Agent Research 12. Multiple PD/PI Leadership Plan. 13. Consortium/Contractual Arrangements 14. Letters of Support 15. Resource Sharing Plan(s) 16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Section IV.6. Appendix

6. Appendix

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

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 16 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.

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 (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123). Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date 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).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; pgotim@cdc.gov for

guidance at least 3 calendar days before the deadline date.
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. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, ***the applicant*** must:
1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
    a. If the status states "***rejected***," do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible. Due

Date for Applications: ***February 23, 2016, FEDEX to CDC OGSTIMS by 5 P.M. EST***

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

Section IV.10. Intergovernmental Review

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

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 United States Government (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.

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

- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.
- Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- Foreign grantees are subject to audit requirements specified in 45 CFR 75. A non-Federal audit is required, if during the grantees fiscal year, the grantee expended a total of $500,000.00 or more under one or more HHS awards (as a direct grantee and/or as a sub-grantee). The grantee either may have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the grantee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements contained in OMB Circular A-133.
- A fiscal Grantee Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.
- If research involves human subjects, funds will be restricted until a Federal Wide Assurance (FWA) and Institutional Review Board Approvals (IRB) are in place.
- 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 Office of Management and Budget (OMB) project determinations by CDC and may require OMB Paperwork Reduction Act (PRA) clearance prior to the start of the project.

12. Other Submission Requirements and Information

Application Submission

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

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

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

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services

(OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), 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 envirc ; to the probability of success? Are the institut urces available to the investigators adequate fc rom unique features of the scientific environme ients?

2. Additional Review Criter

As applicable for the project p dditional items while determining scientific and tecl oriority score, but *will not give separate scores* for these

Protections for Human Subj does not involve one of the six categories of research that e will evaluate the justification for involvement c om research risk relating to their participation according t jects, 2) adequacy of protection against risks, 3) pot ortance of the knowledge to be gained, and 5) data and saf

For research that involves hur e of the six categories of research that are exempt unde) the justification for the exemption, 2) human subjects of materials. For additional information on review of the Human Subjects section, please refer to the NIH/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/grants/additionalrequirements/index.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.

All correspondence should be address to the Provincial Health Director
Telephone 22 44n
Fax: 221447

In reply please quote:
No.....

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

PROVINCIAL MEDICAL OFFICE
P.O BOX 630026
CHOMA

12th December 2015

CDC-RFA-PS10-1010705CONT16
GRANT# 5 U2GPS002856-05

The Technical Information Management Section
2920 Brandywine Road
Mail stop K-68
Atlanta GA 30341

Dear L.C Browning

REF: HARD COPY SUBMISSION FOR SPMO U2GPS002856

Refer to the above subject

The Southern province Medical office through the Center of Disease Control and Prevention has been trying to submit the continuation application for Opportunity No: CDC-RFA-PS10-1010705CONT16, title Improving the capacity of the Southern Province Medical Office in the management of HIV/AIDS/STI/TB under the Presidents Emergency Plan for AIDS relief electronically without success. This is due to the reason we don't the AOR role authorizing us to submit through Grants.gov. Grants office when contacted advised that it's only the very first password that was issued during the first registration that could be used to submit and the PI then is nolonger with SPMO.

Following the advice from your office, please find attached hard copies of the application package including attachments. Below are the Federal domestic numbers and case number

CFDA Number : 93.067

Grants.Gov Case Number : 290742

Thanking you for the support you are rendering to Zambia, in Southern Province.

Yours Sincerely

Dr Sylvia Chinyonga
PRINCIPAL INVESTIGATOR

Mr Nalumango Lubinda
BUSSINESS OFFICIAL

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 (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// 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 five 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) adequacy of veterinary care; 4) 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 5) 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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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/dual-use/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 Plans 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: http://www.cdc.gov/grants/additionalrequirements/index.html. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.
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/applicationresources.html

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 FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- 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.

Section V.5. Announcement and Anticipated Award Dates

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 FOA 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 (http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf).

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.

Awardees 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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/ asfr/ogapa/aboutog/hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects 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-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

AR-26: National Historic Preservation Act of 1966

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

ARs applicable to Conference Awards:

AR-20: Conference Support

AR-27: Conference Disclaimer and Use of Logos

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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/pgo/funding/ grants /additional_ req.shtm.

Dual Use Research of Concern (DURC)

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. September 24, 2014. Available at: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) and required this policy to be implemented by September 24, 2015. DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipients in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy. This policy also applies to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Research funded by CDC involving these agents or toxins 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 may be completed by an Institutional Review Entity

(IRE) identified by the funded institution. Many institutions task their Institutional Biosafety Committees with this responsibility.

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 or cooperative agreement 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. For example, CDC may request that the institution periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal. CDC's Institutional Biosecurity Board (IBB) is responsible for approval of all DURC risk mitigation plans. The award recipient is responsible for adhering to the risk mitigation plan, as approved by CDC.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

Tobacco and Nutrition Policies The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic

cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/ Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm
- http://www.cdc.gov/obesity/strategies/food-serv-guide.html

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

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

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

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

limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- Though awardees retain custody of and primary rights to the data and software developed under these awards, those rights are subject to the Government's rights of access consistent with current DHHS, PHS, and CDC regulations and policies, which state that the Government has the right to: (1) obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and (2) authorize others to receive, reproduce, publish, or otherwise use such data.
- Overseeing all management, administrative, and scientific/programmatic aspects of the research including all data, resources and operations.
- Providing the necessary personnel and supplies to implement components and analyze the results.
- Collaborating with local senior researches, CDC researchers and community-based organizations or similar community liaison for the duration of the project period on several activities such as the development of the data-collection instruments, specimen-collection protocols, and data-management procedures.

- Working with HHS/CDC scientists to refine protocols to improve the study and other proposal components based on reviewers 'comments in the summary statement. The grantee will obtain IRB approval for all collaborators.
- Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants, as determined by the study protocols and the program requirements. The grantee will obtain IRB approval for all collaborators.
- Following study participants as determined by the study protocols.
- Establishing procedures to maintain the privacy of the study participants and confidentiality of the research data. The grantee will obtain IRB approval for all collaborators.
- Agreeing to share data and specimens with CDC scientists, as well as appropriate international partners, such as the World Health Organization.
- In collaboration with HHS/CDC, present at international meetings and publish research findings in peer-reviewed scientific journals.
- Participating in conference with HHS/CDC project official(s) and research team; and attend in-person meeting with HHS/CDC co-investigators
- Collaborating with USG agency scientists to meet objectives of this agreement.
- Meeting the reporting requirements outlined in the Notice of Grant Award.
- Obtain and maintain the appropriate Institutional Review Board (IRB) or ethical review process approvals for all institutions or individuals participating in research involving human subjects.
- Sharing all data and other project and programmatic information with CDC upon request
- Retaining custody of and having primary rights to the data and software developed under this award, subject to U.S. Government rights of access consistent with current DHHS, PHS, and CDC policies.

CDC staff, in Atlanta and assigned to international sites, should have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Monitor the cooperative agreement.
- Collaborate with recipient to establish priorities for the development and implementation of the recipient activities, both among and within each of the areas, through regular meetings and communication.
- Monitor and evaluate scientific and operational accomplishments of this project through frequent consultation, review of technical reports, and interim data analyses.
- Convene workgroups as appropriate to cross-fertilize efforts among different partners
- Assist in designing, developing, and evaluating methods and pilot studies.
- Assist in the protocol development, implementation, data analysis, interpretation of results, and dissemination of findings and pilot demonstration findings including report writing and oral presentation.
- Collaborate with the funded institutions in the development and setting of goals, objectives, effective and innovative strategies and methodologies.
- Collaborate in development of a research protocol for IRB/ethical review by all cooperating institutions that are participating in the research project.
- Obtain and maintain IRB/ethical review approvals as required by CDC when CDC is engaged in research involving human subjects.
- Provide consultation and guidance as needed in support of activities implemented under this agreement.
- Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.
- Collaborate as needed with funded institutions by providing technical assistance in support of activities implemented under this agreement.
- Obtain IRB approvals as required by CDC when CDC is engaged in research involving human subjects.
- Provide 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.

- Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

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

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually 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 awardees 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 awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees 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 (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

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**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** 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 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 project period.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm) http:// grants.nih.gov/grants/ funding/2590/2590.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 contributed 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.

2. Annual Federal Financial Reporting:

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

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date. Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees 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 grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp 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: http:// era.nih.gov/ commons /index.cfm.

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 project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

Stephen Patrick Kachur MD, MPH

Center for Global Health, Division of Parasitic Diseases and Malaria,

Malaria Branch
Telephone: 404-718-4764
Email: spk0@cdc.gov

Peer Review Contact(s)

Hylan Shoob

Scientific Review Officer

Extramural Research Program Office (ERPO)

CGH Science Office

MS D-69, 1600, Clifton Road

Atlanta, GA 30033

Tel: 404-639-4796

E-mail: hshoob@cdc.gov

Financial/Grants Management Contact(s)

Steward Nichols
PGO, International Branch VII

2920 Brandywine Road

Colgate Building, Room 2706

Atlanta, GA 30341
Tel: 770-488-2788

Email: shn8@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements 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 Federal Regulations.

Awards are made under the authorization of Sections of the Public Health Service Act Sections 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b(k)(2)],as amended and under the Code Federal Regulations.

RESEARCH CONTINUATION APPLICATIONS:

All application packages will be FEDEX to the below address:
Please note that your application must arrive to the PGO office with a stamped date no later than (February 23, 2016 on Grants.gov by 5 P.M. EST).

Technical Information Management Section – RFA-GH-15-0060102SUPP16
ATTN: L.C. Browning
2920 Brandywine Road
Mail Stop K-98
Atlanta GA 30341
770-488-2756