
Amendment I, dated December 19, 2013 is being made to the following, in red font on the corresponding page:

Section VIII. Other Information

Page 35 – Added - Summary of Conference Call with Potential Applicants for Funding Opportunity Announcement (FOA): CK14-004 “Reduction of Malaria in U.S. Residents Returning from Overseas Travel to Malaria-Endemic Countries.”

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Part 1. Overview Information

Participating Organization(s)	Centers for Disease Control and Prevention (CDC)
Components of Participating Organizations	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Funding Opportunity Announcement (FOA) Title	Reduction of Malaria in U.S. Residents Returning from Overseas Travel to Malaria-Endemic Countries
Activity Code	U01
Funding Opportunity Announcement Type	New
Funding Opportunity Announcement Number	RFA-CK-14-004
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.084
Category of Funding Activity	Health
FOA Purpose	The purpose of this FOA is to reduce the burden of malaria in U.S. residents who travel overseas to malaria-endemic countries and return to the United States. Consideration should be given to high

	<p>burden areas and populations, such as New York City and persons whose purpose of travel is to visit friends and relatives (VFRs). The objectives of this FOA will be to design qualitative and quantitative studies to document the barriers that exist in various VFR communities leading to increased risk of malaria while traveling, use this knowledge obtained to design and implement targeted intervention programs to reduce disease risk and better protect travelers, document the reduction of disease in these communities, and develop an approach that can be applied to VFR communities nationwide to reduce malaria disease burden. The results of this work should lead to a reduction of malaria cases in the United States.</p>
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Key Dates

Publication Date	To receive notification of any changes to RFA-CK-14-004, 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.
Letters of Intent Due Date	December 19, 2013
Application Due Date	January 21, 2014 by 5:00 PM U.S. Eastern Time. 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).
Anticipated Conference Call	December 12, 2013 at 1:00 PM U.S. Eastern Time.
Scientific Merit Review	March, 2014
Secondary Review	April, 2014

Estimated Start Date	September, 2014
Expiration Date	January 22, 2014
Due Dates for E.O. 12372	March 21, 2014

1. 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 25 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

2. Executive Summary

Purpose. The purpose of this FOA is to reduce the burden of malaria in U.S. residents who travel overseas to malaria-endemic countries and return to the United States. Consideration should be given to high burden areas and populations, such as New York City and persons whose purpose of travel is to visit friends and relatives (VFRs).

Mechanism of Support. Cooperative Agreement

Funds Available and Anticipated Number of Awards. Estimated total funding available including direct and indirect costs for the first year (12 month budget period): \$800,000. Estimated total funding available including direct and indirect costs for the entire project period (5 year project period): \$4,000,000. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

Budget and Project Period. Estimated total funding available including direct and indirect costs for the first year (12 month budget period): \$800,000. Estimated total funding

available including direct and indirect costs for the entire project period (5 year project period): \$4,000,000. The project period will run from 09/01/2014 to 08/31/2019.

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. The number will be one (1).

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

Application Type. New

Special Date(s). A conference call with potential applicants will be held Thursday, December 12, 2013 at 1:00 ET. The bridgeline number is 1-866-620-0420; participant passcode is 8943360.

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

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Announcement Description

Statutory Authority: PHS Act 301(a); 42 U.S.C. Section 241(a)

1. Background and Purpose

Malaria is a potentially life-threatening and fatal disease that remains a significant health problem among U.S. travelers returning from malaria endemic areas of the world. Since the mid-1990's, U.S. malaria surveillance data has consistently reported between 600 and 1080 malaria cases among returning U.S. civilian travelers; the actual numbers of cases exceeds these figures due to gaps in surveillance and specific reporting data. More than 50 deaths attributed to malaria infections have been reported during that same time-span among returning travelers, with additional unreported deaths likely occurring. Among travelers, those described as visiting friends and relatives (VFRs) have been reported to be disproportionately represented among malaria case patients; both studies of travelers and U.S. surveillance data have estimated VFRs to comprise between 35 percent and 70 percent of reported malaria patients. In addition, the New York City area, although geographically small, has consistently reported between 11 percent and 19 percent of all reported U.S. malaria cases since the mid 1990's.

Due to the large numbers of VFRs represented among U.S. malaria patients, new approaches are needed both to examine the reasons for over-representation of malaria specifically among these groups of travelers and then to develop strategies to reduce the disease burden among these populations. This funding opportunity is aimed at facilitating research that will describe the existing barriers that lead to increased risk of acquiring malaria while overseas, and identify potential interventions to reduce the burden of illness among U.S. residents traveling overseas. Consideration should be given to high burden areas, such as New York City and VFRs.

The objectives of this FOA will be to design qualitative and quantitative studies to document the barriers that exist in various VFR communities leading to increased risk of malaria while traveling, use this knowledge obtained to design and implement targeted intervention programs to reduce disease risk and better protect travelers, document the reduction of disease in these communities, and develop an approach that can be applied to VFR communities nationwide to reduce malaria disease burden. The results of this work will lead to a reduction of malaria cases in the United States.

Healthy People 2020 and other National strategic priorities – This FOA addresses the “Healthy People 2020” in the areas of Global Health, Educational and Community-based Programs, and Social Determinants of Health. This FOA is in alignment with HHS/CDC/NCEZID’s aims to prevent disease, disability, and death by a wide range of infectious diseases and HHS/CDC/NCEZID’s tactics of providing leadership in public health, conducting exemplary science, strengthening preparedness efforts, establishing public health policy, sharing vital health information with the public, and building. For more information, please see www.healthypeople.gov and <http://www.cdc.gov/ncezid/>.

Public Health Impact – Malaria is a disease that can result in significant morbidity with a fatal outcome and remains an important disease in U.S. residents returning from overseas areas with malaria risk. VFRs remain a higher risk group among all travelers and places such as New York City remain a high burden area for illnesses. Therefore, the systematic collection of data to better understand and define the barriers in at-risk populations will allow for better understanding of the issues that need to be further addressed. It will allow for the design and

implementation of interventions that could better protect and thus reduce the burden from malaria in these travelers and the overall burden of malaria in the United States.

Relevant work –

Leder K, Black J, O'Brien *et al.* Malaria in travelers: a review of the GeoSentinel surveillance network. *Clin Infect Dis* 2004;39:1104-12.

Hickey PW, Cape KE, Masuoka P, *et al.* A local, regional, and national assessment of pediatric malaria in the United States. *J. Trav Med* 2011;18(3):1195-1982.

Han P, Yanni E, Jentes ES, *et al.* Health challenges of young travelers visiting friends and relatives compared with those traveling for other purposes. *Pediatr Infect Dis J.* 2012; 31(9):915-919.

Mali S, Kachur SP, and Arguin PM. Malaria surveillance – United States, 2010. *MMWR* 2012;61(SS-2):1-17.

2. Approach

The specified objectives of this FOA are to design new research strategies to better understand why malaria cases continue to occur among U.S. residents returning from overseas travel, to develop effective interventions to prevent future malaria cases in these travelers, and to monitor the effectiveness of these interventions. High-risk populations (VFRs) and high-burden areas (such as New York City) should be considered in the scope of work. This work should be able to be maintained and applied to other populations and geographic areas in the United States in order to reduce malaria illness in travelers. Quantitative and qualitative methods should be considered for research and evaluation and novel approaches to risk communication and reduction in barriers among these populations should be implemented as needed.

Objectives/Outcomes – Each of the following objectives should be addressed by the applicant in the research plan to be considered for funding:

- Develop a strategy and systematically collect quantitative and qualitative data to describe existing barriers to effective malaria prevention in travelers. The plan must address describing existing barriers in both travelers and providers and issues related to both pharmacological and non-pharmacological preventions. Specifically outline what methods will be used, such as case-control studies and focus groups, and provide a timeline for data collection and presentation to be accomplished within 2 years of the 5 year project period of this award. The plan should include how materials will be translated into different languages if needed.
- Provide information how data describing existing barriers to effective malaria prevention will be collected from communities with populations who are at greater risk

for disease (VFRs) and geographic areas with greater disease burden (such as New York City) . Describe how information in existing barriers will be differentiated among different subgroups of travelers at increased risk for malaria, such as West African versus South Asian VFRs.

- Based on data collected on barriers from the quantitative and qualitative research efforts described above, previously existing data, and other knowledgeable resources, develop an intervention strategy to reduce the burden of malaria disease among U.S. travelers. The plan should include a provision for using the data on barriers collected, focus on higher risk populations (VFRs) and higher burden areas (such as New York City), and be able to be applied to wider populations and geographic areas in the United States. The plan should also address how different subgroups within communities with higher risk populations (VFRs) and higher burden areas (such as New York City) should be targeted.
- Detail a communication and assessment plan to develop and measure community-level outreach programs to both providers and travelers to reduce barriers associated with malaria prevention and reduce burden of malaria illness. These programs should include novel and approaches to health communication and contain provisions to measure effectiveness. The plan should include how materials will be translated into different languages if needed.
- Describe and detail how both data collection and intervention efforts will engage partners including public health agencies, medical providers, community organizations, schools, and individual travelers. This description should include how efforts will be catered toward variability in and within communities and how materials will be translated into different languages if needed.
- Provide a plan to ensure the security and protection of the identities of the study participants. Approaches to obtain consent for adults and assent from children should be presented.

Target population – Studies and interventions should target U.S travelers to malaria-risk countries and should include higher-risk populations (VFRs) and geographic areas with a greater burden of malaria in travelers (such as New York City).

Collaboration/Partnerships – Applicants are expected to establish partnerships that would facilitate study of existing barriers, design and implementation of interventions, and assessment of effectiveness of programs. Strong consideration should be given to the following: state and local public health agencies, academic institutions, health care providers, schools, community organizations, and businesses accessed by travelers. Applicants should plan to provide evidence of these partnerships (e.g., log-book of communications with community organizations).

Evaluation/Performance measurement – Applicants are expected to describe a project monitoring plan designed to demonstrate progress in project implementation (this should include timelines, schedule for conference calls, onsite meetings, submission of progress reports, etc.). Study and application details should follow the SMART objectives as follows: Specific (who and what will be involved), Measureable (quantify outcomes), Achievable (activities can be accomplished within the given time frame), Realistic (objectives consistent with the scope of the project), and Time-phased (indication of the time frame during which objectives will be met).

Translation plan – The application should describe how significant findings may be used to inform policy or 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 users. The PI should identify the research findings that could inform public health policy or practice and how the findings may be adopted in public health settings. 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 beyond those included in the project.

Questions to consider in preparing this section include:

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

Section II. Award Information

Funding Mechanism	<p>Applications in response to this FOA will be funded using the cooperative agreement mechanism.</p> <p>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.</p>
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Application Types Allowed	<u>New</u> - An application that is submitted for funding for the first time.
Funds Available and Anticipated Number of Awards	<p>Year 1: \$800,000 Year 2: \$800,000 Year 3: \$800,000 Year 4: \$800,000 Year 5: \$800,000</p> <p>Anticipated number of awards: 1</p> <p>Estimated total funding available including direct and indirect costs for the first year (12 month budget period): \$800,000.</p> <p>Estimated total funding available including direct and indirect costs for the entire project period (5 year project period): \$4,000,000.</p>
Ceiling and Floor of Individual Award Range	<p>The ceiling for the individual project award: \$800,000 per year. The floor for the individual project award: None</p> <p>CDC will not accept and review applications with budgets greater than the ceiling amount.</p>
Project Period Length	<p>The project period length is 5 years. 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.</p>

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

CDC Research
Rev. 09/2012

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

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

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits (Other than Institutions of Higher Education)

For- Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

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

For this announcement, applicants **may not** include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Responsiveness: Not applicable.

4. 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:
http://www.dlis.dla.mil/Forms/Form_AC135.asp
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, http://www.grants.gov/applicants/org_step2.jsp.
- [Grants.gov](http://www.Grants.gov)
- [eRA Commons](http://www.eRA Commons)

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

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

5. Universal Identifier Requirements and Central Contractor Registration

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)**, the replacement system for the Central Contractor Registration (CCR) database. 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.

6. 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.

7. Cost Sharing

This FOA **does not** require cost sharing as defined in the HHS Grants Policy Statement (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>).

8. Number of Applications

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

As defined in the HHS Grants Policy Statement, (<http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>), 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.

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. Also, please note that Form C is to be used when downloading the application package.

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 (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard 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/guide/url_redirect.htm?id=12000), 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 and uploaded as Attachment A from the following link: <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>

3. Letter of intent

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

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant
- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

Gregory Anderson, MPH, MS
Extramural Research Program Office
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

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/guide/url_redirect.htm?id=12000) 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_Adobe_VerB.pdf)

must be followed along with any additional instructions provided in the FOA.

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 25 pages.

Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

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/guide/url_redirect.htm?id=12000).

9. Submission Dates and 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/) (<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 CDC PGO TIMS at 770-488-2700; www.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.

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by **Executive Order 12372** (<http://www.archives.gov/federal-register/codification/executive-order/12372.html>). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process. Click on the following link to get the current SPOC list:
http://www.whitehouse.gov/omb/grants_s poc/

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC. Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

12. Other Submission Requirements and Information

Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a grant/cooperative agreement and constitute a

burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

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. Eligibility Information 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 SAM. Additional information may be found in the SF424 (R&R) Application Guide.

Applicants are reminded to enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the 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 this Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO 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?

Does the application focus on VFR population and travel to and from malaria-endemic areas?

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?

Do the investigators have familiarity with travel medicine and malaria illness in particular, communities with populations at higher risk for malaria such as VFRs, and both quantitative and qualitative research methods? Do the investigators have expertise in travel and tropical medicine? Are the investigators knowledgeable with the epidemiology of travelers, including VFRs?

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?

Does the proposal include plans to measure progress toward achieving the stated objectives and does the application detail SMART objectives? Is there a study work plan and time line included? Does the approach include collaborative efforts with state and local public health agencies, health care providers, community organizations, and other institutions and partners to accomplish stated goals?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Are there letters of support from all relevant participating organizations and entities demonstrating that working relationship?

Does the application demonstrate the ability to access and collaborate with public health agencies, medical providers, and community organizations involved with VFR communities?

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#) , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review

criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (<http://www.cdc.gov/OD/foia/policies/inclusio.htm>) and the policy on the Inclusion of Persons Under 21 in Research (<http://aops-mas-iis.cdc.gov/Policy/Doc/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.

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.

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/od/foia/policies/sharing.htm>. 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/od/pgo/funding/budgetguide.htm>.

Collaborations

Reviewers will consider the applicant's ability to collaborate with state and local public health agencies, medical providers, community organizations, and institutions and groups to accomplish stated goals.

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

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- Relevance of high burden areas and populations and persons whose purpose of travel is to visit friends and relatives (VFRs).

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://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>).

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 described in [Section IV.5. 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://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf>).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2010](#)

[AR-12: Lobbying Restrictions](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)
[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](#)

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.access.gpo.gov/nara/cfr/cfr-table-search.html>

To view brief descriptions of relevant CDC requirements visit:
http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

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/asfr/ogapa/acquisition/effspendpol_memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), 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 Web site, www.USASpending.gov (<http://www.usaspending.gov/>). For the full text of the requirements, please review the following website:

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf

Plain Writing Act

The Plain Writing Act of 2010 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.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)
 - <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
 - <http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>

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.

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 Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), 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.

Projects that request approval or significant input from CDC for the development of study design, research methods, participant recruitment, or information collection instruments may require review and approval by the Office of Management and Budget (OMB). OMB approval may require up to 9 months. During the OMB approval process, the awardee may not pursue information collection activities.

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

- PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In Addition the PI/PD must provide to CDC Program the abstracts or manuscripts prior to any publication related to this funding.
- PUBLICATIONS: The grantee will not seek to publish results and findings from this project without prior approval and clearance from CDC.
- Providing scientific and management oversight for the overall project at his/her site, including research design and conducting data collection, quality control, data analysis and interpretation.
- Conducting the appropriate training of study staff.
- Including plans for a study data safety monitoring board.
- Obtaining and maintaining the appropriate Institutional Review Board approvals for all institutions or individuals participating in the research project.
- Protecting any confidential information received and provision of a specific contact person for participants.

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- Working with CDC project scientists to obtain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
 - Ensuring safety of study staff.
 - Providing the necessary personnel and supplies to implement the study and analyze the results.
 - Participating in at least monthly conference calls with the CDC project officer.
 - Participating in conference calls with the CDC Project Scientists to collaborate on the development of the research protocols and provide progress updates.
 - Working with CDC scientists to consider refining protocols in order to improve the science based on reviewers' comments in the summary statement.
 - Collaborating and sharing data with CDC.
 - Presenting and submitting any studies (or its various components) for publication in a peer-reviewed journal with CDC collaborators if CDC contribution merits this within 6-12 months after completion of the study and presentation at scientific meetings within 6 months of the conclusion of the study.
 - Budgeting for at least one meeting at CDC per calendar year to present data; Grantees should budget from within their award for travel to CDC.

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

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

- Provide background information on other relevant studies conducted by or at the HHS/CDC.
- Assist with the development of a research protocol involving human subjects for review by an Institutional Review Board (IRB) by all cooperating institutions that are participating in the research project, including required CDC IRB review when CDC is engaged in research involving human subjects. The protocol will serve as an initial review and annually thereafter until the research project is completed.
- Monitor scientific and operational accomplishments of this project through frequent telephone contact, the review of technical reports, and interim data analyses.
- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application.
- Based on this, HHS/CDC will make recommendations aimed at solving problems and improving the quality and timeliness of the research activities.

Areas of Joint Responsibility include:

- CDC, in conjunction with the PI for the awarded project will establish regular contact within 60 days of the award. Required conference calls will be implemented to:

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- Provide guidance to investigators regarding study implementation and conduct.
 - Establish goals and promote collaborations and coordinate research.
 - Evaluate progress of the projects.

Additionally, a Scientific Program Officer in the Extramural Research Program Office, NCHHSTP/OD will be responsible for the normal scientific and programmatic stewardship of the award, as described below:

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

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 Central Contractor Registry; 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://dhhs.gov/asfr/ogapa/grantinformation/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, <http://www.cdc.gov/od/pgo/funding/forms.htm> 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 each budget period.**
- 3. A final progress report**, invention statement, equipment/inventory report, and the expenditure data portion of the Federal Financial Report (FFR) Standard Form ("SF") 425 Form are required **within 90 days of 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 inform policy or 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 users. The PI should identify the research findings that informed 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 inform public health policy or practice?
 - How will the project improve or effect the translation of research findings into policy or practice?
 - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs 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, to 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 be 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).

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- 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 each budget period. 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: <http://www.cdc.gov/od/pgo/funding/grants/eramain.shtm>.

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: <http://era.nih.gov/commons/>. Organizations not yet registered can go to <https://commons.era.nih.gov/commons/registration/registrationInstructions.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 public health policy and 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, to inform policy, technology or systems improvement 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)

Procurement and Grants Office

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am - 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

Amy Yang, PhD

Extramural Research Program Office

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

CDC Research

Rev. 09/2012

1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8836
Fax: 404-718-8822
Email: vdz9@cdc.gov

Peer Review Contact(s)

Gregory Anderson, MPH, MS
Extramural Research Program Office
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
Fax: 404-718-8822
Email: GAnderson@cdc.gov

Financial/Grants Management Contact(s)

Michael Vance
Procurement and Grants Office
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2920 Brandy Wine Road, MS E15
Atlanta, GA 30341
Telephone: (770) 488-2686
Fax: (770) 488-2868
Email: mav5@cdc.gov

Section VIII. Other Information

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 PHS Act 301(a); 42 U.S.C. Section 241(a).

Summary of Conference Call with Potential Applicants for Funding Opportunity Announcement (FOA): CK14-004 “Reduction of Malaria in U.S. Residents Returning from Overseas Travel to Malaria-Endemic Countries.”

Introductory Comments

Any scientific or technical questions should be addressed to Amy Yang (vdz9@cdc.gov). Any questions on the financial/grants management/eligibility aspect should be addressed to Michael Vance (mav5@cdc.gov). Questions regarding the Peer Review process should be addressed to Greg Anderson (gca5@cdc.gov). Their contact information can be found in the FOA in Part 2, Section VII “Agency Contacts”.

Submission Dates and Times

Please see Part 2, Section IV (Application and Submission Information) for helpful information on submitting your application.

Letter of Intent due: December 19, 2013 (submit via email to Greg Anderson: gca5@cdc.gov)

Applications due: January 21, 2014 by 5:00pm ET

Eligibility Information

Please see Part 2, Section III.1 (Eligible Applicants) for questions regarding eligible applicants.

Required Registrations

Please see Part 2, Section III.4 (Required Registrations) for information on required registrations.

Other Tips

Please submit your application at least five days before the deadline to allow for error correction. No extensions will be granted due to applications being rejected because of submission errors. Please be aware that one should receive three notifications post-submission which include confirmation of submission to grants.gov, transit of application from grants.gov to eRA Commons, and final confirmation that the application is in eRA Commons. Please go to eRA Commons to make sure your application is complete.

Potential applicant should pay close attention to Part 2, Section V.1 (Criteria). The criteria must be addressed – these are the criteria that will be used to ultimately score the application. Failure to provide required information could result in an unfavorable score. Please also pay close attention to Part 2, Section I.2 (Approach). Applicants must respond to ALL objectives listed.

Please remember that the Research Plan Narrative is limited to 25 pages. Also please remember that a 5-year Research Plan and a budget for each year must be submitted.

It is anticipated that there will be 1 award. The estimated total funding available for Year 1 is \$800,000. The estimated total funding for the entire project period is \$4,000,000. The ceiling amount is \$800,000 per year. CDC will not accept or review applications with budgets greater than the ceiling amount.

Awards issued under this FOA are contingent upon availability of funds.

Questions and Answers

1) Question: Since there will only be one award, would that mean that it would be in an applicant's best interest to partner with New York City?

Answer: Submitted proposals would be best served to include all of the potential partners that are needed to bring together a successful collaborative effort.

2) Question: It quickly becomes obvious that the greatest number of reported cases is in New York City. Is your approach focused on a specific geographical region within the U.S., or rather the subpopulation mentioned (US nationals who visit friends and relatives)?

Answer: Our anticipated endpoint is to see interventions that would reduce the number of malaria cases in persons whose purpose of travel is to visit friends and relatives (VFR). We would hope to see the burden amongst these populations reduced. If a group of partners could show a way of doing that in the specific populations or in other geographic locations that would be fine. There is the potential for engaging a large variety of populations, and doing so would also be appropriate.

3) Question: When sending in the letter of intent (LOI), is it required that we already know who are partners will be?

Answer: No, although it is helpful to provide as much of this information as possible.

4) Question: My understanding is that CDC is on 1 year money. That said, there is no guarantee of 5 year funding. What is a reasonable expectation of work to be completed in year 1?

Answer: Money is always contingent upon program funds. Funding becomes available to our group on a yearly basis. Each year the amount of funds available for continuation would be determined. We would not expect five years' worth of work to be completed in the first year in anticipation that funding may not proceed. In the first year, we would expect a "pro-rated" amount of overall project to be completed.

5) Question: The FOA states that there will be 1 awardee. Do you anticipate other awards should additional funding become available?

Answer: This is very unlikely, but always possible. The scoring/ranking results of the Special Emphasis Panel will remain valid for 12 months in the event this scenario does occur.

6) Question: Why is the award as large as it is?

Answer: Our judgment is that the money is appropriate for the scope of the work expected.

7) Question: As this is a cooperative agreement, will CDC be the owner of all data?

Answer: No. Please see the middle of page 28 where it states that awardees will retain custody of data and software subject to Government rights of access.

8) Question: In other FOAs there is sometime involvement by the funding organization. Is that the case here?

Answer: Absolutely. Please see Part 2, Section VI.4 where the Roles and Responsibilities of awardees and CDC employees are described.

9) Question: Given the scope and importance of this work, is there any way the receipt date can be extended?

Answer: No, the receipt date will not be extended.