

Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases Extramural Research Program Office

Spatially Scalable Integrated Tick Vector/Rodent Reservoir Management to Reduce Human Risk of Exposure to Ixodes scapularis Ticks Infected with Lyme Disease Spirochetes

RFA-CK-16-002

Application Due Date: 02/02/2016

Spatially Scalable Integrated Tick Vector/Rodent Reservoir Management to Reduce Human Risk of Exposure to Ixodes scapularis Ticks Infected with Lyme Disease Spirochetes

RFA-CK-16-002

TABLE OF CONTENTS

Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Emerging and Zoonotic Infectious Diseases Extramural Research Program Office (NCEZID ERPO)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Funding Opportunity Announcement (FOA) Title

Spatially Scalable Integrated Tick Vector/Rodent Reservoir Management to Reduce Human Risk of Exposure to Ixodes scapularis Ticks Infected with Lyme Disease Spirochetes

Activity Code

U01 Research Project Cooperative Agreements

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-CK-16-002

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

93.942

Category of Funding Activity:

Health

FOA Purpose

To advance knowledge of the impact of environmentally-based tick/pathogen control conducted on single versus multiple adjacent properties, in relation to human landscape use patterns and tick exposure locations, on the risk of human exposure to ticks infected with Lyme disease spirochetes.

Key Dates

Publication Date: **To receive notification of any changes to RFA-CK-16-002, 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: **01/04/2016**

Application Due Date: **02/02/2016**

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: **04/14/2016**

Secondary Review: **05/10/2016**

Estimated Start Date: **09/01/2016**

Expiration Date: **02/03/2016**

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

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

Executive Summary

- **Purpose.** To advance knowledge of the impact of environmentally-based tick/pathogen control conducted on single versus multiple adjacent properties, in relation to human landscape use patterns and tick exposure locations, on the risk of human exposure to ticks infected with Lyme disease spirochetes.
- **Mechanism of Support.** Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards.** Estimated total funding (direct and indirect) is $1,600,000. A single award is anticipated. 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 the 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.** Total funding (direct and indirect) for the first year (12-month budget period) is $300,000. Estimated total funding (direct and indirect) for the entire 4-year project period is $1,600,000. The project period will run from 9/01/2016 to 8/31/2020.
- **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 are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI per application. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.
- **Number of Applications.** Eligible applicant institutions may submit only one application.
- **Application Type.** New.
- **Special Date(s).** Not applicable.
- **Application Materials.** See **Section IV.1** for application materials. Please note that Form C is to be used when downloading the application package. http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY:

(770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Section 301, 42 U.S.C 241(a).

1. Background and Purpose

Background: Lyme disease, caused primarily by the spirochete *Borrelia burgdorferi* sensu stricto in the United States, is the most commonly reported vector-borne disease in the United States with >30,000 confirmed or probable cases reported annually and a recent estimate suggesting that ten-fold more cases may occur. Primary Lyme disease foci occur in the Northeast and Upper Midwest, where the blacklegged tick, *Ixodes scapularis*, is the primary enzootic vector of *B. burgdorferi* and, particularly with respect to the nymphal stage, the primary bridging vector to humans. There is currently no human vaccine against *B. burgdorferi*. In contrast to mosquito control, which is implemented at the scale of communities or neighborhoods, the responsibility for tick control rests firmly on individual homeowners. Options for protection of individuals or single residential properties include personal protective measures to reduce the likelihood of tick contact (avoidance of high risk microhabitats, protective clothing, repellents, etc.) or to prevent transmission of *B. burgdorferi* by an attached tick (prompt tick removal, antibiotic prophylaxis) and various environmentally-based control methods. Environmentally-based control methods include: 1) landscape modification to reduce the risk of tick exposure (brush clearing, leaf litter removal, reduction of tree/forest canopy, deer fencing, placing play structures in microhabitats inhospitable for host-seeking ticks, etc.); 2) application of biological or chemical control agents directly to the ground substrate/vegetation to kill host-seeking ticks; and 3) targeting of rodent reservoirs to suppress enzootic *B. burgdorferi* transmission and reduce the number of infected ticks. These environmentally-based control approaches are all scalable in that they can be implemented on either single or multiple adjacent residential properties. In contrast, deer reduction or deer-targeted acaricides are community-wide approaches that are not scalable down to single residential properties.

Tick/pathogen control driven by individual homeowners results in complex patchworks of residential properties on which control is undertaken versus not undertaken, intermingled with public use lands lacking tick/pathogen control measures. Consequently, human landscape use patterns are key determinants for risk of exposure to infected ticks based on time spent in protected areas (on properties where control measures are successfully implemented) versus non-protected settings (residential properties or public lands without control measures). The residential property itself, which may be considered the primary risk setting for acquisition of Lyme disease in the Northeast, can be protected as outlined above. However, there may be substantial additional risk of exposure to infected ticks from nearby non-protected areas. Examples of common behaviors that may lead to tick bites, unless personal protection measures are taken, include children living on partly protected residential properties but ranging in their play outside of the protected portion of the property (e.g., across a treated woods/lawn edge into a wooded non-treated area) or people routinely hiking or walking dogs on nearby public access land trails and in natural areas.

Previous studies have demonstrated dramatic reductions of the acarological risk of exposure to Lyme disease spirochetes (i.e., the abundance of host-seeking *I. scapularis* infected with *B. burgdorferi*) on single residential properties based on application of chemical control agents to kill host-seeking ticks and/or treatment of rodent reservoirs to reduce their tick loads and suppress enzootic spirochete transmission. These studies have not included assessments of human spatial activity patterns or tick-human encounter locations, nor have they explored potential beneficial effects of treating multiple adjacent versus single properties, particularly for rodent reservoir targeted interventions where the effect can be assumed to span the rodent home range. This raises several important questions including: 1) what is the interplay of adjacent treated

and non-treated settings in terms of acting as sinks and sources, respectively, for enzootic *B. burgdorferi* transmission and production of infected host-seeking ticks?; and 2) to what extent is tick/pathogen control on single or multiple adjacent residential properties counteracted by additional tick exposures in other non-treated settings?

Purpose: To advance knowledge of the impact of environmentally-based tick/pathogen control conducted on single versus multiple adjacent properties, in relation to human landscape use patterns and tick exposure locations, on the risk of human exposure to ticks infected with Lyme disease spirochetes.

Healthy People 2020 and other National Strategic Priorities

The proposed research addresses the Healthy People 2020 focus area relating to "Immunization and Infectious Diseases" (focus area 14), specifically to "Reduce Lyme Disease" (section 14-8). The FOA aims to help reduce Lyme disease by improved spatial implementation of existing tick vector and rodent reservoir control methods on residential properties, and by better defining human-tick encounter locations in Lyme disease endemic areas thus increasing awareness of high risk microhabitats that call for increased vigilance in personal protective measures or tick/rodent-targeted control efforts.

Public Health Impact

Key expected outcomes include: guidance for homeowners in Lyme disease endemic areas regarding the added value of tick/pathogen control on multiple adjacent properties, which could potentially be implemented by homeowner associations; and improved knowledge of human-tick encounter locations in Lyme disease endemic areas to inform the use of personal protection measures.

Relevant Work

1. Hayes, E. B., and J. Piesman. 2003. How can we prevent Lyme disease? New England Journal of Medicine 348: 2424-2430.
2. Schulze, T. L., R. A. Jordan, C. J. Schulze, S. P. Healy, M. B. Jahn, and J. Piesman. 2007**.** Integrated use of 4-poster passive topical treatment devices for deer, targeted acaricide applications, and Maxforce TMS bait boxes to rapidly suppress populations of *Ixodes scapularis* (Acari: Ixodidae) in a residential landscape. Journal of Medical Entomology 44: 830-839.
3. Stafford III, K. C. 2007. Tick management handbook. An integrated guide for homeowners, pest control operators, and public health officials for the prevention of tick-associated disease. The Connecticut Agricultural Experiment Station, New Haven, CT, Bulletin No. 1010.
4. Eisen, R. J., J. Piesman, E. Zielinski-Gutierrez, and L. Eisen. 2012. What do we need to know about disease ecology to prevent Lyme disease in the Northeastern United States? Journal of Medical Entomology 49: 11-22.

2. Approach

Objectives/Outcomes

Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

The proposed research approach is expected to be scientifically sound and statistically robust. Key questions that the proposed research is expected to address include: 1) the extent of added protection for a treated residential property that is bordered by other treated residential properties versus non-treated properties; and 2) to what extent is tick/pathogen control on single or multiple adjacent treated residential properties counteracted by human-tick encounters that occur in non-treated settings (on residential properties and/or public land)?

A key expected outcome of the research is guidance for homeowners regarding the added value of

tick/pathogen control on multiple adjacent properties (i.e., whether treatment of multiple adjacent properties provides an added protective effect for an individual property within this group compared to treatment of a single property surrounded by non-treated properties). Should such an added value be demonstrated, there is the possibility for homeowner associations or other similar groups to implement coordinated tick/pathogen control on multiple adjacent properties.

Specific requirements for the approach of research projects funded under this FOA:

- The research team is expected to include expertise in medical entomology, small mammal biology, human behavioral science, and statistics/study design.
- The research is expected to be conducted within a county or multiple counties that in the last 3 years can be considered to be endemic for Lyme disease, with a combined incidence of reported or probable Lyme disease exceeding 10 per 100,000 population per year.
- The research is expected to be conducted within general areas with previously documented dense populations of host-seeking *I. scapularis* nymphs ($\geq 0.1/m^2$).
- The research is expected to be conducted in residential settings in an area where tick exposures on residential properties are thought to account for the majority of Lyme disease cases.
- The project will extend across four (4) spring-summer periods. The first spring-summer period is expected to be devoted to developing baseline data for acarological risk of exposure to *I. scapularis* and *B. burgdorferi*, and for human-tick encounters. The second and third spring-summer periods are expected to include implementation of the integrated tick/pathogen management strategy outlined below together with the continued collection of data for acarological risk of exposure to *I. scapularis* and *B. burgdorferi*, and for human-tick encounters. The fourth and final spring-summer period is expected to be devoted to collection of follow-up data for acarological risk of exposure to *I. scapularis* and *B. burgdorferi*, and for human-tick encounters.
- Experimental groups of residential properties must include: 1) non-treated control properties, 2) single treated properties, and 3) multiple adjacent treated properties. Clusters of multiple adjacent treated properties should be designed such that at least one of the treated properties within each cluster is surrounded on all sides by other treated properties.
- To facilitate comparison with other CDC-funded studies that evaluated single control methods, the integrated tick/pathogen management strategy used in this research must combine the use of a commercially available synthetic pyrethroid acaricide for application to the ground substrate and vegetation with the use of a commercially available rodent reservoir-targeted acaricide application product with potential for impacting both mice and chipmunks. Pesticide application is expected to be conducted by or under the guidance of a licensed pesticide applicator, and to comply with any pesticide label and use guidelines and existing regulatory terms.
- Acaricide application to the ground substrate and vegetation must be performed using hydraulic high-pressure spray equipment; and be done twice per year, just prior to the onset of the nymphal activity season and then repeated 4-6 weeks later.
- Rodent-targeted acaricide application must cover the entire period of nymphal and larval seasonal activity, tentatively from early May to late September. Sampling of host-seeking ticks must minimally include nymphal *I. scapularis* collected during the peak of their seasonal activity period.
- As the integrated control approach can be assumed to impact the entire residential property, the design for sampling of host-seeking ticks should reflect acarological risk across the main types of habitats found on the study properties (e.g., open lawn, lawn edge along woods, lawn edge along rock wall, woods edge bordering on lawn, woods, and sturdy ornamental vegetation); and data should be collected as to be traceable back to those habitats.
- Detection of *Borrelia burgdorferi* and other human pathogens in collected host-seeking ticks will be an area of joint responsibility in the research and potentially carried out by CDC staff.
- A power analysis is required to justify the proposed sample size for number of properties to be included in the research with regard to assessing reductions in the abundance of host-seeking *I. scapularis* nymphs, *B. burgdorferi* infection rate in host-seeking *I. scapularis* nymphs and, **most**

importantly, the abundance of *B. burgdorferi*-infected host-seeking *I. scapularis* nymphs.

- Human activity space must be assessed in sufficient detail to minimally clarify usage of the participant's own residential property versus other nearby residential properties and other potential tick exposure habitats on public use land during the time of year when nymphs are most active.
- Human tick encounter locations – for ticks found crawling on or attached to study participants – must minimally be classified as most likely being on the participant's own residential property versus other nearby residential properties and other potential tick exposure habitats on public use land. Further consideration must be given to attempt to determine more specific likely tick encounter locations, including in what microhabitat on the participant's own residential property the tick encounter most likely occurred, and how far distant from the home encounters occurred on other residential properties or on public lands, and what type of activity most likely resulted in the tick exposure.
- The majority of ticks encountered by the study participants should be recovered and identified to species and life stage.
- If deemed feasible following consultation with the applicants institutional review board for human subjects research, *I. scapularis* ticks recovered from humans should be examined for the presence of *B. burgdorferi* to allow for comparison of infection rates in ticks from treatment and control groups (at the experimental group level, not linking back to individual participants).
- The number of individuals from the properties falling into each of the three above-mentioned experimental groups that are recruited to participate in the studies on human activity space and tick encounters must be justified statistically to ensure that the results will not be superficial or inconclusive due to low sample sizes.
- A project timeline should be included to demonstrate that the proposed work can be completed during the funding period.
- As this is a cooperative agreement, CDC staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards – this is further detailed under Section VI.4. Cooperative Agreement Terms and Conditions of Award of this FOA.

Minimal outcomes that applicants are expected to achieve by the end of the funding period:

- Quantification and statistical comparison of acarological risk of exposure to *I. scapularis* and *B. burgdorferi* (minimally abundance of host-seeking *I. scapularis* nymphs, *B. burgdorferi* infection rate in host-seeking *I. scapularis* nymphs, and abundance of *B. burgdorferi*-infected host-seeking *I. scapularis* nymphs) for the three above-mentioned experimental scenarios (non-treated control properties; single treated properties; and multiple adjacent treated properties, including separation of the treated properties that are surrounded by other treated properties on all sides versus treated properties bordering on treated properties on some sides but non-treated areas on other sides).
- Determination of whether treatment of multiple adjacent properties provides an added protective effect, with respect to the above-mentioned acarological risk measures, for an individual property within this group (including separation of the treated properties that are surrounded by other treated properties on all sides versus treated properties bordering on treated properties on some sides but non-treated areas on other sides) compared to treatment of a single property surrounded by non-treated properties.
- Quantification and statistical comparison of human-tick encounters for the three above-mentioned experimental scenarios (non-treated control properties; single treated properties; and multiple adjacent treated properties, including separation of the treated properties that are surrounded by other treated properties on all sides versus treated properties bordering on treated properties on some sides but non-treated areas on other sides).
- Determination of whether treatment of multiple adjacent properties provides an added protective effect, with respect to human-tick encounters, for an individual property within this group (including separation of the treated properties that are surrounded by other treated properties on all sides versus treated properties bordering on treated properties on some sides but non-treated areas on other sides) compared to treatment of a single property surrounded by non-treated ones.

- Determination of the extent to which treatment of single or multiple adjacent properties covers the human activity space with respect to exposure to tick risk habitat during the nymphal activity period.
- Determination of specific settings (residential properties and public use land) and specific locations (e.g., lawn/woods edge; lawn; garden; ornamental vegetation away from the lawn/woods edge; woods directly outside the lawn/woods edge; and public use trail in wooded land) where human-tick encounters most frequently occur.
- Additional work to determine acarological risk measures for other *I. scapularis*-borne pathogens (e.g., *Anaplasma phaagocytophilum* and *Babesia microti*)among the three experimental scenarios is encouraged but not a requirement.
- Additional work to determine *B. burgdorferi* infection rates for rodents among the three experimental scenarios is encouraged but not a requirement.

Target Population

- The research is expected to be conducted within a county or multiple counties that in the last 3 years can be considered to be endemic for Lyme disease, with a combined incidence of reported or probable Lyme disease exceeding 10 per 100,000 population per year.
- The research is expected to be conducted in residential settings in an area where tick exposures on residential properties are thought to account for the majority of Lyme disease cases.

Collaboration/Partnerships

- The research team is expected to include expertise in medical entomology, small mammal biology, human behavioral science, and statistics/study design.
- Pesticide application is expected to be conducted by or under the guidance of a licensed pesticide applicator, and to comply with any pesticide label and use guidelines and existing regulatory terms.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims based on a four-year research project period. The grantee will collaborate with CDC to: (1) establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the applicant's project plan, and (2) develop and implement project performance measures that are based on specific programmatic objectives. Also, funded PIs must submit an annual progress report showing their activities and outcomes based on their overall research goals and timeline. For more information on required Reporting, please see Section VI of this FOA.

Specific Requirements

- Evaluation activities must include determination of acarological risk measures (minimally abundance of host-seeking *I. scapularis* nymphs, *B. burgdorferi* infection rate in host-seeking *I. scapularis* nymphs, and abundance of *B. burgdorferi*-infected host-seeking *I. scapularis* nymphs) as well as quantification of human-tick encounters and assessment of human activity space with respect to tick encounter locations and exposure to tick risk habitat during the peak nymphal activity period.
- The method used for detection of *B. burgdorferi* sensu stricto in ticks must be adequate to distinguish this spirochete from other known *B. burgdorferi* sensu lato spirochetes that occur in the eastern U.S. and the relapsing fever spirochete *Borrelia miyamotoi.*
- The proposed scale of the evaluation, i.e., the number of residential properties and individuals recruited in the experimental groups, must be justified by power analyses or other statistical assessments.

Translation Plan

Dissemination of research findings is expected to occur via: 1) publication of research results in peer-reviewed scientific journals, 2) presentation of research results at scientific conferences, and 3) inclusion of key findings on CDC's webpage for Lyme disease (http://www.cdc.gov/lyme/).

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $1,600,000

Year 1: $300,000

Year 2: $500,000

Year 3: $500,000

Year 4: $300,000

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: $300,000 Per Budget Period

Award Floor: $100,000 Per Budget Period

Total Project Period Length: 4 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:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities

Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

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

sid=512ff78311f427c00454772dcf21523a&rgn=div8
&view=text&node=48:1.0.1.6.34.0.1.18& idno=48

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. Special Eligibility Requirements

Applicant organizations that request funding above the ceiling amount of the award will not be forwarded to peer review or considered for funding.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications submitted under this funding opportunity announcement must not include activities that overlap with simultaneously-funded research already awarded to applicants under other awards.

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 (PGO 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.

3. Letter of Intent

Due Date for Letter of Intent: **01/04/2016**

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

Office of the Associate Director of Science

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/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.

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/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 CDC PGO 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: **02/02/2016**

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

10. Intergovernmental Review (E.O. 12372)

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_spoc/.

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.
For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

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

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

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.

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 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?

Have the investigators made voluntary additions to the stated research scope in order to enhance the potential impact of the research?

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 a successful track record in field research relating to control of *Ixodes scapularis* and *Borrelia burgdorferi?*

Is there a person assigned who will work full-time on the project to ensure that logistics are handled in a timely manner?

Does the application demonstrate that this is a research team with documented previous collective experience (including publication history) with all of the following: 1) field-based control studies targeting host-seeking *Ixodes scapularis* as well as rodent reservoirs for *Borrelia burgdorferi*, 2) development and use of questionnaire instruments relating to human behavior, and 3) assessment of human landscape use patterns?

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?

Are there innovative aspects to the proposed research in terms of the spatial study design, particularly the spatial distribution of properties in the three experimental groups (non-treated control, single treated properties, and multiple adjacent treated properties)?

Are there innovative aspects to the proposed research in terms of the methodology to be used to define human activity space and specific tick encounter locations?

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?

Is the selection of general study area adequately justified?

Are the proposed designs to determine study outcomes adequately justified statistically (e.g., with power analyses)?

Is the proposed methodology to assess human activity space and tick encounter locations adequate to meet the stated research goals?

Does the application address the “Specific requirements for the approach of research projects funded under this FOA” listed under Section I.2. Approach?

Does the application address the three “Specific Requirements” listed under Section I. Evaluation/Performance Measurement?

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 pre-existing links with proposed study communities to ensure recruitment success?

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.

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.

As part of the Biohazards assessment, reviewers will evaluate whether the research proposed qualifies as Dual Use Research of Concern. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research of concern is a subset of dual use research 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 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

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

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/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.

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/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 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.

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 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:

- AR-1: Human Subjects Requirements
- AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3: Animal Subjects Requirements
- AR-7: Executive Order 12372 Review
- AR-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

The following are additional policy requirements relevant to this FOA:

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/ 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: https:// www.fsrs.gov/.

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.cdc.gov/ nccdphp/dnpao/hwi/toolkits/ tobacco/index.htm
- http://www.cdc.gov/nutrition/index.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.

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 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:

- Obtaining and maintaining the appropriate Institutional Review Board approvals for all institutions or individuals participating in the research project.
- Obtaining and maintaining the appropriate approvals for use of a rodent-targeted acaricide.
- Obtaining and maintaining the appropriate approvals for trapping and processing of rodents, if applicable.
- Identifying Lyme disease endemic residential areas for the research, and recruiting homes and individuals to participate in the study.
- Ensuring that the numbers of homes and individuals recruited for the study are sufficient to achieve the research objectives.
- Developing a timeline for study activities that will address each research objective within the proposed funding period.
- Developing, and making available to the CDC Project Officer, standard operating procedures (SOPs) for all methodologies used in the field or laboratory to generate the data needed to achieve the research objectives.
- Developing statistically sound evaluation models for the data to be collected and analyzed.
- Interacting cooperatively with the Center Project Officer in all stages of the research.
- Holding informal quarterly conference calls with the CDC Project Officer to regularly monitor performance against approved project objectives.
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or

present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

- Serves as CDC's subject matter expert for the proposed research.
- Makes recommendations to the Scientific Program Officer regarding the annual request for continuation application and requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application.
- Provides technical assistance, oversight and feedback to the PD(s)/PI(s) to ensure that the research objectives are met including: reviewing standard operating procedures for field and laboratory methodologies, assessing the suitability of the proposed field research area, ensuring that the final study design has sufficient statistical power, and that appropriate statistical evaluation methods are used to analyze the collected data.
- Regularly monitors performance against approved project objectives.
- Assists the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Areas of Joint Responsibilities include:

- Detection of *Borrelia burgdorferi* and other human pathogens in collected host-seeking ticks.
- Publication of research in scientific journals and on the CDC's webpage for Lyme disease (http://www.cdc.gov/lyme/), as warranted.
- Collaborating in the development of human subjects research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.

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

- Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award;
- Serves 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;
- Makes recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application;
- Carries out continuous review of all activities to ensure objectives are being met;
- Attends committee meetings and participates in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitors 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 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: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era). 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/ 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)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Program Official/ Scientific Research Contact

Amy Yang, PhD

Extramural Research Program Office

Office of the Associate Director for Science

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: 404-718-8836

Fax: 404-718-8822

Email: vdz9@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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

Louvern Asante

Office of Grant Services

Office of Financial Resources

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2920 Brandy Wine Road, MS E15

Atlanta, GA 30341

Telephone: 770-488-2835

Fax: (770) 488-2868

Email: lha5@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.

Public Health Service Act, Section 301, 42 U.S.C 241(a).