

Centers for Disease Control and Prevention

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

Epicenters for the Prevention of Healthcare Associated Infections (HAIs) - Cycle II
RFA-CK-15-004
Application Due Date: 06/01/2015

Epicenters for the Prevention of Healthcare Associated Infections (HAIs) - Cycle II

RFA-CK-15-004

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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

Epicenters for the Prevention of Healthcare Associated Infections (HAIs) - Cycle II

Activity Code

Applications in response to this FOA will be funded using the **U54** activity code.

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-CK-15-004

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

93.823

Category of Funding Activity:

Health

FOA Purpose

The purpose of this FOA is to expand the number of CDC Prevention Epicenters to translate basic, epidemiologic and technologic discoveries into new strategies for preventing healthcare-associated transmission of Ebola and/or infectious pathogens (viral or bacterial) that can be spread by mechanisms similar to Ebola. This might include, but is not limited to, project proposals that focus on the effectiveness of personal protective equipment against such pathogens, healthcare worker self-contamination with pathogens, or the role of the healthcare environment in pathogen transmission.

This announcement was amended to include the Summary of the Conference Call held on Tuesday, April 16, 2015 with Potential Applicants and Answers to Questions from Potential Applicants in red text in Section VIII. of the FOA.

Key Dates

Publication Date: **To receive notification of any changes to RFA-CK-15-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: 05/01/2015

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. Please see Section IV.3 of this FOA for further information.

Application Due Date: **06/01/2015**

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: **06/30/2015**

Secondary Review: **07/07/2015**

Estimated Start Date: **09/30/2015**

Expiration Date: **06/02/2015**

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

Required Application Instructions

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

Note: The Research Strategy component of the Research Plan is limited to 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.** The purpose of this FOA is to expand the number of research institutions in the CDC Prevention Epicenters Program to translate basic, epidemiologic and technologic discoveries into new strategies for preventing healthcare-associated transmission of Ebola and/or infectious pathogens (viral or bacterial) that can be spread by mechanisms similar to Ebola. This might include, but is not limited to, project proposals that focus on the effectiveness of personal protective equipment against such pathogens, healthcare worker self-contamination with pathogens, or the role of the healthcare environment in pathogen transmission.
- **Mechanism of Support:** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** Estimated total funds available, to include direct and indirect costs for the entire project period, is $11,000,000. The project period will be three years. It is anticipated that there will be five awards. Awards issued under this FOA are contingent upon the availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** There will be a 36-month budget period, and all funds for the three-year project period will be awarded as a lump sum at the time of initial award. The average estimated total funding (direct and indirect) for each award (36-month budget period) will be $2,200,000. The estimated total funding (direct and indirect) for all awards in the entire project period will be $11,000,000. The project period will run from 9/30/2015 to 09/29/2018. 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.

- **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 be only one PD/PI for this project.
- **Number of Applications.** Each eligible applicant institution may submit only one application.
- **Application Type:** New.
- **Special Date(s).** A teleconference call with potential applicants will be conducted on Thursday, April 16, 2015 at 2:00 PM Eastern Time. The call-in number and password is as follows: 1-866-662-8986; 8378091.
- **Application Materials.** See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

42 U.S.C. Section 247b(k)(2) and 42 U.S.C. Section 241(a)

1. Background and Purpose

Transmission of infectious pathogens in healthcare settings results in significant morbidity and mortality among patients treated in U.S. healthcare institutions and adds billions of dollars to healthcare costs. In addition, recent history has shown that infectious disease transmission within healthcare settings can help propagate major epidemics caused by pathogens such as Ebola virus, SARS coronavirus, MERS coronavirus, novel strains of influenza, and bacterial pathogens such as *Clostridium difficile* and multidrug resistant bacteria. Recent advances in preventing healthcare-associated infections have resulted from better implementation of existing recommendations for prevention practice in healthcare settings. However, recent experiences with rare and novel pathogens in US healthcare settings suggest that existing prevention strategies for preventing device- and procedure-associated infections may have insufficient effectiveness in preventing transmission of high-consequence microorganisms in healthcare settings. In light of this gap, additional innovation is needed to advance the prevention of transmission of infectious diseases in healthcare settings.

The CDC Prevention Epicenters Program has been established to develop, implement and evaluate the effectiveness of epidemiologically-based strategies to improve healthcare quality and patient safety. CDC has found the Prevention Epicenters Program to be an extremely productive model for aligning public health needs with the innovative research capacity of academic partners. Recent Prevention Epicenters'work has focused on a translational research framework for HAI prevention research proposed by Pronovost, *et al*, 2011 (1), which characterizes five translational phases:

- Phase T0, in which discoveries relevant to the prevention of adverse healthcare events are made through surveillance, outbreak investigation, epidemiologic studies, and technologic advances;
- Phase T1, in which T0 discoveries are used to develop novel candidate interventions and perform early testing of their efficacy or effectiveness in a small sample of patients or in limited healthcare settings;
- Phase T2, in which the evidence base for candidate interventions is broadened and strengthened sufficiently to include the novel intervention in evidence-based guidelines;
- Phase T3, in which evidence-based guidelines are moved into practice, through delivery, dissemination, and diffusion research, and
- Phase T4, in which guidelines are implemented on a broad scale (e.g., nationally) and evaluated for evidence of improvement in population health.

Recent advances in prevention of HAIs have been largely the result of Phase T3 research, which led to large-scale improvement in implementation of existing prevention recommendations in healthcare facilities. However, even when fully implemented, current prevention recommendations are limited in their ability to prevent transmission, and many are unproven or not well-suited for a wide range healthcare settings and clinical situations (2-8). Therefore, the CDC Prevention Epicenters program has focused on early translational research (e.g., Phases T0-T2) to expedite identification and development of novel or enhanced strategies for preventing acquisition of infectious diseases in healthcare settings. Through this funding opportunity announcement, CDC hopes to address gaps in infection prevention identified during the 2014-2015 outbreak of Ebola virus disease for the purpose of improving the capacity to prevent and control both current and future infectious threats.

The CDC Prevention Epicenters Program operates as a collaborative multicenter research network of investigators who collaborate with CDC and with one another to address emerging or evolving public health research needs related to the prevention of transmission of pathogens that cause HAIs among patients and healthcare personnel. The intent of the program is to provide CDC with a resource for meeting public health research needs by creating close collaborative ties between investigators with interest in preventing infections acquired in healthcare. Whereas investigator-initiated projects will not necessarily involve other Epicenter investigators, each funded Epicenter is expected to provide regular reports on plans and progress pertaining to their individual projects, and provide opportunities for comment and technical support, if needed, from other Prevention Epicenter Investigators and from CDC personnel. Participants in the program are encouraged to identify multicenter collaborative opportunities that enhance the ability to meet the goals and objectives of applications. Applicants funded under this FOA will serve as a member of the multicenter CDC Prevention Epicenters Program.

The CDC Prevention Epicenters collaborative research network is overseen by the Epicenters Program Steering Committee. This committee will be comprised of Principal Investigators and one CDC representative who will serve as a consultant to the committee. The steering committee will serve in an advisory and consultant role to individual investigators as needed and also will discuss and oversee multicenter project ideas that emerge during the course of the program. A well-developed Program Steering Committee is integral to the Program's success. Participation in the steering committee includes, but is not limited to, active participation in conference calls, webinars and in-person meetings (i.e., grantee meetings and special projects meetings).

The purpose of this FOA is to expand the number of CDC Prevention Epicenters to translate basic, epidemiologic and technologic discoveries into new strategies for preventing healthcare-associated transmission of Ebola and/or infectious pathogens (viral or bacterial) that are spread by similar mechanisms as Ebola. This might include, but is not limited to, project proposals that focus on effectiveness of personal protective equipment against such pathogens, healthcare worker self-contamination with pathogens, or the role of the healthcare environment in pathogen transmission. Whereas Ebola is known to be transmitted primarily by direct and indirect contact, droplet transmission may occur in certain settings, such as those that might be expected to generate splashes to unprotected mucous membranes, or during certain aerosol-generating procedures. For this reason, research supporting new or improved strategies for

prevention of transmission of pathogens transmitted via droplet route would also fall under the purpose of this FOA.

References

1. Pronovost PJ, Cardo DM, Goeschel CA, Berenholtz SM, Saint S, Jernigan JA. A research framework for reducing preventable patient harm. Clin Infect Dis. 2011 Feb 15; 52(4):507-13.

2. Centers for Disease Control and Prevention (CDC). Vital Signs: Carbapenem-Resistant Enterobacteriaceae. MMWR Morb Mortal Wkly Rep. 2013 March 8, 62(09): 165-170.

3. Centers for Disease Control and Prevention. Clinical Inquiries Regarding Ebola Virus Disease Received by CDC — United States, July 9–November 15, 2014. MMWR Morb Mortal Wkly Rep. 2014 December 12, 63(49); 1175-1179.

4. Centers for Disease Control and Prevention. Ebola Virus Disease Cluster in the United States — Dallas County, Texas, 2014. MMWR Morb Mortal Wkly Rep. 2014 November 21, 63(46); 1087-1088.

5. Centers for Disease Control and Prevention. Surveillance and Preparedness for Ebola Virus Disease — New York City, 2014. MMWR Morb Mortal Wkly Rep. 2014 October 17, 63(41);934-936.

6. Sharif-Yakan A, Kanj SS. Emergence of MERS-CoV in the Middle East: Origins, Transmission, Treatment, and Perspectives. Spindler KR, ed. *PLoS Pathogens* 2014;10(12):e1004457. doi:10.1371/journal.ppat.1004457.

7. Cheng VC. Chan JF, To KK, Yuen KY. Clinical management and infection control of SARS: lessons learned. Antiviral Res. 2013 Nov;100(2):407-19.

8. Lessa FC, Gould CV, McDonald LC. Current status of *Clostridium difficile* infection epidemiology. Clin Infect Dis. 2012 Aug;55 Suppl 2:S65-70.

Healthy People 2020 and other National Strategic Priorities

On November 5th, 2014, President Obama asked Congress to consider an emergency appropriation request for Fiscal Year (FY) 2015 that included funds to implement a comprehensive strategy to contain and end the Ebola outbreak and accelerate global capability to prevent the spread of future infectious diseases. Given recent experience showing that infectious disease transmission within healthcare settings can help propagate major epidemics caused by pathogens such as Ebola virus, SARS coronavirus, MERS coronavirus, novel strains of influenza, bacterial pathogens such as *Clostridium difficile* and multidrug resistant bacteria, a comprehensive strategy to contain future outbreaks must include improved strategies for preventing transmission of microorganisms in healthcare settings. This funding opportunity announcement addresses the national strategic priority set out in the approved emergency appropriation request for FY 2015 to address knowledge gaps that were identified during the Ebola response. The National Center Emerging and Zoonotic Infectious Diseases (NCEZID) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020". This FOA supports and addresses the HP 2020 goal to " Prevent, reduce, and ultimately eliminate healthcare-associated infections (HAIs)" (http://www.healthypeople.gov/2020/topics-objectives/topic/healthcare-associated-infections).

Public Health Impact

Research funded by this FOA will support innovative strategies to improve the capacity to prevent and control the spread of Ebola and other infectious pathogens with similar modes of transmission in healthcare settings, thereby helping to prevent and control both current and future outbreaks.

Relevant Work

CDC's Prevention Epicenter Program: For the past 18 years, the CDC Prevention Epicenter Program has been active in the field of HAI prevention research. Fourteen institutions have participated, producing 181 publications related to the prevention of infections in healthcare settings. Information on relevant work by the CDC Prevention Epicenter Program, including selected citations, can be found at: http://www.cdc.gov/HAI/epiCenters/.

Also please see:

Center for Disease Control and Prevention: Ebola (Ebola Virus Disease) Internet Resources: http://www.cdc.gov/vhf/ebola/

Centers for Disease Control and Prevention: FY 2015 Ebola Response Funding: http://www.cdc.gov/fmo/topic/Budget%20Information/

Centers for Disease Control and Prevention. Surveillance and Preparedness for Ebola Virus Disease — New York City, 2014. MMWR Morb Mortal Wkly Rep. 2014 October 17, 63(41);934-936.

2. Approach

Research applications should include a three-year research program design that develops and tests innovative strategies for preventing transmission of infectious pathogens in healthcare settings. This FOA is not intended to support projects that focus primarily on strategies for preventing healthcare-associated infections that may result from a patient's resident flora (i.e., many device- and procedure-associated infections). Rather, proposed research should focus on preventing spread of potentially pathogenic microorganisms among patients and healthcare workers in healthcare settings. Applications should emphasize innovative research activities consistent with translational research phases T1 and early T2 (i.e., research that seeks to build upon existing T0 discoveries by moving them into first or early application of candidate interventions in healthcare settings and patient populations), but may also include foundational T0 work that expands understanding of the mechanisms of spread of infectious pathogens in healthcare settings. Applicants should demonstrate a plan to maintain ongoing collaboration between scientists with T0 expertise and those with T1/T2 expertise. It is expected that a strong collaboration between basic, epidemiologic or laboratory scientists and clinical scientists will help ensure ability to develop and sustain an iterative research program. It is anticipated that the proposed research will, over the course of the 36-month budget and project period, result in evidence for effective interventions and include results that are mature enough to merit either inclusion in CDC prevention recommendations or investment in larger confirmatory clinical studies.

Objectives/Outcomes

Identify and validate novel interventions that involve new translation of epidemiologic, technologic, or basic science observations into strategies that effectively prevent transmission of infectious pathogens in healthcare settings, including Ebola virus and/or other viral or bacterial pathogens that can spread by similar mechanisms as Ebola.

Examples of research topics that might be considered for funding include, but are not limited to, the following:

- Assessing the effectiveness of personal protective equipment (PPE) against transmission of infectious pathogens and identifying novel strategies to improve the effectiveness of PPE;
- Identifying factors related to healthcare worker self-contamination with pathogens during the course of their work and the potential role of such contamination in healthcare setting disease transmission;
- Identifying strategies for preventing healthcare worker self-contamination;
- Determining the role of contamination of the healthcare environment in pathogen transmission and identifying novel strategies for preventing transmission resulting from environmental contamination;
- Use of molecular, epidemiologic or other markers to enhance basic understanding of how pathogens spread in healthcare settings, including but not limited to, patient-to-healthcare worker, healthcare

worker-to-patient, patient/healthcare worker-to-environment, environment-to-patient/healthcare worker, patient-to-patient, and other pathways of transmission;
- Research supporting better understanding and prevention of transmission of pathogens via droplets, including exposures that might result from activities that generate splashes to unprotected mucous membranes, or from certain aerosol-generating procedures.

To best meet the objectives of this FOA and the goals of the CDC Prevention Epicenter Program, applicants/institutions should possess the following research capabilities and characteristics:

- Have an established program to conduct HAI prevention research;
- Have research expertise and academic leadership in healthcare epidemiology and infection control or HAI prevention research;
- Have access to an infrastructure that is conducive to performing a wide variety of potential studies that evaluate the impact of interventions to prevent healthcare-associated infections. This includes demonstrated ability to conduct research that involves multiple healthcare facilities, potentially those affiliated within a healthcare system (such as those affiliated with a healthcare provider company that owns or operates multiple facilities, health maintenance organizations, etc.);
- Have access to multiple facilities willing to participate in research of this type, allowing for more flexibility in responding to public health research needs, more robust validation and generalization of findings and innovations than is possible in a single facility. Access to facilities across the spectrum of healthcare is also desirable (e.g., academic medical centers, community hospitals, long-term care facilities, long-term acute care centers, dialysis units and ambulatory surgery centers);
- The applicant should demonstrate how multiple facilities within each healthcare system will be involved in the development and validation of both interventions and reporting measures. Links to local and state health departments are strongly encouraged;
- Have the ability to collect electronic health record information from all of the facilities that are eligible and willing to collaboratively participate in HAI prevention research, including information sufficient to determine relevant clinical outcomes and process of care measures related to those outcomes;
- Letters of Support, Memoranda of Understanding or Memoranda of Agreement from participating collaborators are encouraged.

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

Target Population

Patients and healthcare workers in healthcare settings.

Collaboration/Partnerships

The CDC Prevention Epicenters Program operates as a research consortium that creates a multicenter network of CDC Prevention Epicenter investigators who collaborate with CDC and with one another to address emerging or evolving public health research needs related to the prevention of transmission of pathogens that cause HAIs among patients and healthcare personnel. The intent of the program is to provide CDC with a resource for meeting public health research needs by creating close collaborative ties between investigators with interest in preventing infections acquired in healthcare. Whereas investigator-initiated projects will not necessarily involve other Epicenter investigators, each funded Epicenter is expected to provide regular reports on plans and progress pertaining to their individual projects, and provide opportunities for comment and technical support, if needed, from other Prevention Epicenter Investigators and from CDC personnel. Participants in the program are encouraged to identify multicenter collaborative opportunities that enhance the ability to meet the goals and objectives of individual investigator proposals.

Evaluation/Performance Measurement

Applicants should outline appropriate plans to collect information that can be used to evaluate the impact of the CDC Prevention Epicenter Program. The following should be included in the application as part of the evaluation plan:

- Identification of emerging research questions to address knowledge gaps related to prevention of transmission of infectious pathogens in healthcare settings;
- Development of study protocols that address knowledge gaps related to prevention of transmission of infectious pathogens in healthcare settings;
- Publication of research findings that address knowledge gaps related to prevention of transmission of infectious pathogens in healthcare settings.

Translation Plan

When relevant to the goals of the research project, the PI should describe in the application how the significant findings of the research may be used to inform the translation of research to policy or practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that could inform public health policy or practice and how the findings may be adopted in public health settings. This section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

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

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: $11,000,000

Estimated total funding available, to include direct and indirect costs for the entire project period, is $11,000,000. The project period will be 36 months.

Anticipated Number of Awards: 5

It is anticipated that there will be five awards.

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

Award Ceiling: $2,200,000 Per Budget Period
Award Floor: $1,500,000 Per Budget Period
Total Project Period Length: 3 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
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)

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

Institutions/organizations that receive funds under "Epi-Centers for the Prevention of Healthcare-Associated Infections, Antimicrobial Resistance and Adverse Events (U54)" FOA CK11-001 are not eligible to apply.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications that request funds above the ceiling of the award will not move forward to peer review or be eligible for funding.

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.

Each eligible applicant institution may submit only one application.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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

These forms can be downloaded and uploaded as Attachment A from the following link: http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent: **05/01/2015**

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

Name of the Applicant

Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity announcement

The letter of intent should be sent to:

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; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's

application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:
If an application submission was unsuccessful, ***the applicant*** must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
    b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **06/01/2015**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the 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 relating to the conduct of research involving human subjects will be restricted until appropriate assurances and Institutional Review Board approvals are in place.

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?

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?

Does the research team include expertise in T0 work that is relevant to the focus of the novel intervention strategies being studied and also include expertise in clinical research, particularly in the field of healthcare epidemiology?

Have the investigators documented a significant track record of publication in the area of healthcare infection control and healthcare epidemiology?

Does the research team include expertise in surveillance, outbreak investigation and epidemiologic study of adverse events in healthcare settings?

Does the applicant demonstrate academic leadership in healthcare epidemiology and infection control or HAI prevention research?

Does the applicant have an established program to conduct HAI prevention research?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Does the proposed study move basic, epidemiologic, or technological discoveries (i.e., existing T0 discoveries) into first or early application of candidate interventions for prevention of transmission of infectious pathogens in healthcare settings and patient populations?

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?

Does the applicant demonstrate a centralized Institutional Review Board (IRB) approval process for all facilities that are eligible and willing to collaboratively participate in prevention research as part of this award?

Does the approach, over the 36-month budget and project period, address a gap in effective strategies for preventing transmission of infectious pathogens in healthcare settings?

Does the application include metrics for assessing goals for the entire funding period and approximate timelines for the entire 36-month budget and project period?

Does the approach, over the 36-month budget and project period, address a CDC HAI research priority area identified in the section of this FOA labeled “Objectives/Outcomes”?

Are there plans to incorporate a centralized IRB approval process for all the facilities that are eligible and willing to collaboratively participate in HAI prevention research as part of this award?

Does the proposed research focus on preventing spread of potentially pathogenic microorganisms among patients and healthcare workers in healthcare settings rather than on strategies for preventing

healthcare-associated infections that often result from a patient's resident flora (i.e., device- and procedure-associated infections)?

Does the application include a plan to maintain ongoing interdisciplinary collaboration between scientists with the above expertise and those developing novel candidate interventions, performing efficacy testing and developing evidence-based guidelines for healthcare over the entire 36-month budget and project period?

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?

Has the applicant demonstrated an infrastructure that is conducive to performing a wide variety of potential studies that evaluate the impact of interventions to prevent transmission of infectious pathogens in healthcare, including the demonstrated ability to conduct research that involves multiple healthcare facilities?

Has the applicant demonstrated the ability to collect health information from all facilities that are eligible and willing to collaboratively participate in HAI prevention research - including information sufficient to determine relevant clinical outcomes and process of care measures related to those outcomes?

Has the applicant demonstrated ability to perform HAI prevention research within a group of facilities with an existing capacity for electronic healthcare recordkeeping and/or electronic clinical and laboratory data exchanges?

Does the applicant provide evidence of multi-facility collaboration in HAI prevention research within a healthcare system, or strong evidence for the administrative capacity to coordinate and standardize intervention and data collection strategies across a large number of facilities?

Has the applicant demonstrated an existing capacity for electronic healthcare recordkeeping and electronic clinical and laboratory data exchanges within the participating facilities in the healthcare system?

Does the applicant have demonstrated access to multiple facilities willing to participate in research of this type, allowing for more flexibility in responding to public health research needs and allow for more robust validation and generalization of findings and innovations than is possible in a single facility?

Does the applicant have demonstrated access to facilities across the spectrum of healthcare (e.g., academic medical centers, community hospitals, long-term care facilities, long-term acute care centers, dialysis units, and ambulatory surgery centers)?

Does the applicant demonstrate how multiple facilities within each healthcare system will be involved in the development and validation of both interventions and reporting measures (links to local and state health departments is required)?

Does the application include Letters of Support, Memoranda of Understanding, or Memoranda of Agreement from collaborating partners?

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#ar25. 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.

Listed below are funding preferences, in priority order, that may be taken into consideration in the funding recommendation process. Specifically, applicants may be recommended for funding out of rank order based on the following preferences:

•Funding recommendations may consider the diversity of research topics and/or patient populations being studied. In order to avoid redundant lines of research and maximizing the number of research topics being addressed by the program, applications that increase the diversity of research topics for the program may be given funding preference as long as each research topic addresses a research priority area identified in Part 2. Section I.2. “Objectives/Outcomes” of this FOA.

•Funding recommendations may also consider geographic diversity (e.g., applications that increase the diversity of geographic regions defined by the Department of Health and Human Services, http://www.hhs.gov/about/regionmap.html) in order to maximize the program’s flexibility in addressing evolving public health research needs that may vary by geographic region.

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:

The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collection (i.e., posing similar questions or requirements via surveys, questionnaires, telephonic requests, focus groups, etc.) from 10 or more non-Federal entities/persons, including States, are subject to PRA requirements and may require CDC to coordinate an Office of Management and Budget (OMB) Information Collection Request clearance prior to the start of information collection activities. This would also include information sent to or obtained by CDC via forms, applications, reports, information systems, and any other means for requesting information from 10 or more persons; asking or requiring 10 or more entities/persons to keep or retain records; or asking or requiring 10 or more entities/persons to disclose information to a third-party or the general public.

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

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-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

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/

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

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/ chronicdisease/resources/ guidelines/food-service- guidelines.htm

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

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

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

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

- Actively participating, as a member of the Epicenters Steering Committee: This includes attending annual grantee meetings in Atlanta that are convened by CDC staff, participating in regular communication with other members of the steering committee through regular teleconferences (potentially weekly), and participating in steering committee activity regarding Public Health Initiated projects involving multiple Epicenter investigators;
- Conducting a three-year research program designed to develop and test novel prevention strategies related to the prevention of HAIs;
- Serving in an advisory or consultant role to other Epicenter investigators with regard to their individual investigator-initiated projects, as needed;
- Collaborating with other Epicenter investigators in developing and implementing multicenter Public Health Initiated Projects;
- Assisting in determining the scope and magnitude of newly emerging infectious disease threats by conducting rapid surveys of their patient and provider populations, as needed, during the funding period - the purpose of this activity is to collaborate with CDC to provide a mechanism for rapid assessment across a wide variety of US healthcare institutions of conditions as they relate to newly emerging infectious disease threats;
- Budgeting for each budget period to include travel costs for one to two staff (i.e., the Principal Investigator, the Co-Investigator or Project Manager) to attend three, 2-day planning and steering meetings in Atlanta, Georgia with CDC staff and other cooperative agreement awardees;
- Obtaining the appropriate Institutional Review Board (IRB) approvals for all institutions or individuals participating in the research project and obtaining IRB review on an annual basis until the research project is completed;
- Ensuring all surveys, questionnaires, and other information collected from respondents includes a valid OMB Control Number, a burden statement, and government use of the information collected in each statement, when applicable - Paperwork Reduction Act (PRA) eligibility will depend upon the evaluation and reporting methods to be used for each activity and, if applicable, project managers will submit a PRA determination form for each of the activities and/or contact the NCEZID OMB Coordinator as soon as the data collection instruments and methods for evaluation have been developed;
- Obtaining IRB review, when applicable;
- Retaining custody of and having 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;
- Developing study protocols, implementation plans and standard operating protocols to accomplish the objectives of the research plan;
- Conducting the appropriate training of partners whose knowledge of the study and/or direct participation will be needed;
- Providing the necessary personnel and supplies to conduct and manage the study and analyze the results;
- Collecting and managing data in a format standardized across sites and compatible with other funded grantees;
- Providing scientific and management oversight for the overall project at his/her site, including research design and conduct, data collection, quality control, data analysis and interpretation;
- Collaborating and sharing data with other awardees and CDC;
- Describing research findings at regular intervals in project reports and publishing the results in the peer-reviewed literature with CDC collaborators, as warranted;
- Participating in protocol development and approval with other funded awardees and CDC to pool results across study sites;
- PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily

represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program the abstracts or manuscripts prior to any publication related to this funding;
- PUBLICATIONS/PRESENTATIONS: The grantee will not seek to publish or present results or findings from this project without prior approval and clearance from CDC.

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

- Collaborating, as appropriate, with the recipient in all stages of the program and providing programmatic and technical assistance;
- Offering assistance to the recipient in all aspects of the science, including active participation in protocol development;
- Serving as a consultant to the Epicenters Program Steering Committee;
- Providing technical assistance and support for the design, implementation, and evaluation of research and program activities;
- Facilitating and assisting in the development of a research protocol for IRB review by all cooperating institutions participating in the research project - a CDC engagement determination will determine if the CDC IRB will also need to approve the protocol;
- Facilitating data analysis, interpretation of results, and dissemination and publication of results;
- Carrying out continuous review of all activities to ensure project objectives are being met;
- Collaborating with grantee to disseminate study results at national or international meetings and publishing research findings in peer-reviewed scientific literature, if contribution so merits;
- Providing background information on other relevant studies conducted at HHS/CDC or HHS National Institutes of Health;
- Providing technical assistance in the areas of epidemiological methods, clinical research, statistical analysis, and laboratory diagnostics.

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

- Named in the NoA as the Program Official to provide overall scientific and programmatic stewardship of the award;
- Serving 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;
- Making recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application;
- Carrying out continuous review of all activities to ensure objectives are being met;
- Attending committee meetings and participating in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.

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.

NOTE: Non-competing continuation grant progress reports are not applicable under this Funding Opportunity Announcement (FOA). Grantees awarded under this FOA will be required to submit a semi-annual performance report during the 36-month project period. The frequency of required performance and financial reporting and the required format will be provided with the award documents and will supersede the "Yearly Non-Competing Grant Progress Report" submission instructions outlined in this FOA.

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:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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

Program Official / Scientific Research Contact(s)
Deborah Loveys, 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: 404-718-8834

Fax: 404-718-8822

Email: dloveys@cdc.gov

Peer Review Contact(s)
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(s)
Mattie Jackson

Procurement and Grants Office

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

2920 Brandy Wine Road, MS E15

Atlanta, GA 30341

Telephone: (770) 488- 2696

Fax: (770) 488-2868

Email: mij3@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.

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

Summary of the Conference Call held on Tuesday, April 16, 2015 with Potential Applicants for Funding Opportunity Announcement (FOA): CK15-004 "Epi-Centers for the Prevention of Healthcare Associated Infections (HAIs) – Cycle II" and Answers to Questions from Potential Applicants

A. Introductory Comments

Any scientific or technical questions should be addressed to Deborah Loveys (hft6@cdc.gov). Any questions on financial, grants management, or eligibility aspects should be addressed to Mattie Jackson (mij3@cdc.gov). Questions regarding the Peer Review process should be addressed to Greg Anderson (gca5@cdc.gov). Their contact information can be found in the FOA, Part 2, Section VII. "Agency Contacts". Information on application submission is listed in Section IV. "Application and Submission Information".

B. Eligibility Information

Please see Part 2, Section III. "Eligibility Information" for questions regarding eligible applicants.

C. Required Registrations

Please see Part 2, Section III. 6. "Required Registrations" for information on required registrations.

D. Other Information

Please submit your application at least five days before the deadline to allow for error correction. No extensions will be granted due to applications that are rejected because of submission errors.

Potential applicants should pay close attention to Part 2, Section V. "Application Review Information, 1. Criteria". The criteria must be addressed – these are the criteria that will be used by reviewers to score the application. Failure to provide required information could result in an unfavorable score. Please also pay close attention to Part 2, Section I. "Funding Opportunity Description, 2. Approach".

Please remember that the Research Plan Narrative is limited to 25 pages. Also remember to submit a 3-year Research Plan and a budget for each year.

It is anticipated that there will be 5 awards. The estimated total funding available for the entire project period is $11,000,000. The floor amount for the budget period is $1,500,000, including direct and indirect costs. The ceiling amount for the budget period is $2,200,000, including direct and indirect costs. Awards issued under this FOA are contingent upon the availability of funds.

E. Questions and Answers:

1) Question: Epi-centers often do other projects than those originally described. Is there an expectation that the application should include the potential for other projects to arise?

Answer: Your application should provide enough information on your team and institution to demonstrate the abilities and infrastructure requirements to meet the requirements of the FOA. Your proposed research activities should be limited to the objectives and outcomes outlined in the CK15-004 FOA.

2) Question: Do we respond to all objectives – even the examples?

Answer: You are not required or expected to respond to the examples of research activities listed in this FOA. You are expected to respond to and address the broader research objectives and outcomes outlined in the FOA and further detail the proposed research activities to be funded in your application.

3) Question: What is the plan for these sites, after the 3 year period, for integration into existing Epi-centers?

Answer: Future plans for Epi-Center program funding is not within the scope of this conference call. We do not have any information to provide to you on future funding opportunities.

4) Question: Can you tell us which biosketch format should be used?

Answer: Please use the new format as described in the SF424(R&R) application guide (Pages I-88 and I-89 at: http://grants.nih.gov/grants/funding/424/sf424_rr_guide_general_verc.pdf).

5) Question: Are the currently funded Epi-centers being re-competed or will they continue to exist as per their current funding terms?

Answer: Please refer to Part 2. Sections III.1-3. of the FOA for applicant eligibility information. Institutions/organizations that receive funds under "Epi-Centers for the Prevention of Healthcare-Associated Infections, Antimicrobial Resistance and Adverse Events (U54)", FOA CK11-001, are not eligible to apply. CK11-001 awardees are currently funded through the end of the project period date of 2/29/2016.

6) Question: It seems that many of the currently funded Epi-centers have PIs that work in a healthcare or academic institution. Is that required for Cycle II?

Answer: The FOA identifies preferred research capabilities and attributes of Epi-center institutions in Part 2. Section I.2. Approach - Objectives / Outcomes. The criteria for eligible Project Directors/Principal Investigators is defined in Part I. Executive Summary and applicant eligibility information is identified in Part 2. Section III of the FOA.

7) Question: There may be some projects that may result from early projects in the 3 year period. Can we address this in the application?

Answer: Applications received for this FOA should contain proposals for research activities that can be completed within the 36-month budget and project periods identified. There may be cases where proposed research activities will be performed in sequence or where a later activity may rely on the outcome of an earlier activity. In cases where subsequent activities could vary based on earlier outcomes, it may be beneficial to identify or outline alternative approaches for implementation of later activities.

8) Question: How are you expecting the different Epi-centers to work together?

Answer: The scope of research activities funded under the CK11-001 and CK15-004 FOAs do not allow for overlap or cooperative work between Cycle I and Cycle II Epi-center institutions. Consistent with previously funded Epi-center program activities, the CDC Prevention Epicenters collaborative research network will be overseen by the Epicenters Program Steering Committee. This committee will be comprised of Principal Investigators and one CDC representative who will serve as a consultant to the committee. The steering committee will serve in an advisory and consultant role to individual investigators as needed and also will discuss and oversee multicenter project ideas that emerge during the course of the program.

9) Question: Should these meetings be planned into the budget?

Answer: Yes. Please refer to Section VI.4 Cooperative Agreement Terms and Conditions of Award; "Budgeting for each budget period to include travel costs for one to two staff (i.e., the Principal Investigator, the Co-Investigator or Project Manager) to attend three, 2-day planning and steering meetings in Atlanta, Georgia with CDC staff and other cooperative agreement awardees".

10) Question: When will the existing Epi-centers be re-competed?

Answer: Future plans for funding other FOAs are not within the scope of this conference call. We do not have information to provide on the potential for future funding.

11) Question: Can you please confirm what the budget limit per project per year is and if this limit is for direct costs only, or total project costs?

Answer: Under Part 2. Section II. Award Information, each award under this FOA will be issued with a 36-month budget/project period. The FOA identifies a floor and ceiling amount (per awardee per budget

period) of $1,500,000 and $2,200,000, respectively. The floor and ceiling amounts are identified as total (direct and indirect) budget amounts.

12) Question: Regarding budget proposals, are we to take the $2,200,000 ceiling per budget period and divide that by the anticipated number of awards (i.e., 5); meaning that the ceiling per project is $440,000?

Answer: No, the ceiling amount for the 36-month budget period (which is also a 36-month project period) is $2,200,000 per applicant application. The estimated total amount of funding for ALL anticipated applicant awards will be $11,000,000 (5 awards x $2,200,000).

13) Question: Can a staff faculty member from an institution funded under CK11-001, but who is not currently involved in that funded research, be included in our application for funding under the CK15-004 FOA?

Answer: A staff/faculty member from an institution funded under CK11-001 who is not currently involved in that funded research is allowed to serve in a contractual or consultant capacity on a CK15-004 application from another institution.

14) Question: Can I submit a research application under this FOA in conjunction with a colleague from another institution if my colleague's institution is also submitting an application for this FOA?

Answer: Under Part 1. Overview Information, Executive Summary, there can only be one Principal Investigator for applicant research proposals and each eligible applicant institution can only submit one application.