



**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, Antimicrobial Resistance and Adverse  
Events

RFA-CK-16-004

Application Due Date: 01/15/2016

Epicenters for the Prevention of Healthcare Associated Infections, Antimicrobial Resistance and Adverse  
Events

RFA-CK-16-004

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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, Antimicrobial Resistance and Adverse Events

### Activity Code

[U54](#) Research Project Cooperative Agreement

### Funding Opportunity Announcement Type

New

### Funding Opportunity Announcement Number

RFA-CK-16-004

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

93.084

### Category of Funding Activity:

Health

### FOA Purpose

The purpose of this funding opportunity announcement (FOA) is to support the translation of basic, epidemiologic and technologic discoveries into new strategies for preventing and decreasing the incidence of healthcare-associated infections (HAIs), antimicrobial resistance (AR) and other adverse events in all types of healthcare facilities in the United States.

**This FOA has been amended to include information regarding the increased availability of funds (pages 2, 3, 9 and 10 of this revised FOA), the increased number of collaborative projects allowed for each Epicenter from four (4) to twelve (12)(page 8 of this revised FOA), the justification for the increased funds (page 12 of this revised FOA) and the format for application submission (page 16 of this revised FOA).**

### Key Dates

**Publication Date:** To receive notification of any changes to RFA-CK-16-004, return to the synopsis page of this announcement at [www.grants.gov](http://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:** 12/15/2015

**Application Due Date:** 01/15/2016

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

**Scientific Merit Review:** 03/08/2016

**Secondary Review:** 04/05/2016

**Estimated Start Date:** 07/01/2016

**Expiration Date:** 01/16/2016

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

### Required Application Instructions

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

**Note:** The Research Strategy component of the Research Plan is limited to 10 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 Funding Opportunity Announcement (FOA) is to support the translation of basic, epidemiologic and technologic discoveries into new strategies for preventing and decreasing the incidence of healthcare-associated infections (HAIs), antimicrobial resistance (AR) and other adverse events in all types of healthcare facilities in the United States. CDC is interested in building upon research gains accomplished under FOA CK11-001: Epi-Centers for the Prevention of Healthcare-Associated Infections, Antimicrobial Resistance and Adverse Events over the past 5 years.

Under this FOA, each eligible applicant Epicenter must propose a Single Epicenter Core Research Project (“Core Project”) that aligns with CDC’s HAI Prevention Research Agenda (please see Part 2. Section I.2 “Objectives/Outcomes” of this FOA). Additionally, each applicant Epicenter must propose to lead at least one, or up to three, Multicenter HAI Prevention Research Collaborative Project(s) (“Collaborative Project(s)”), each with up to four other Epicenters collaborating as Participating Epicenters.

**Mechanism of Support.** Cooperative Agreement.

**Funds Available and Anticipated Number of Awards.** The estimated total funding available is **\$22,500,000** (direct and indirect costs) for the first 12-month budget period and **\$43,500,000** (direct and indirect costs) for the entire 4-year project period.

The estimated funds available for a Single Epicenter Core Project is \$500,000 per award per year. The anticipated number of Core Project awards is up to 5.

The funds available for a Collaborative Project is based on its size and complexity and is estimated to be:

- **\$500,000** for a small-sized project (range **\$300,000 to \$700,000** with a budget period of up to 2 years);
- **\$1,350,000** for a medium-sized project (range **\$700,000 to \$2,000,000** with a budget period of up to 3 years); and

- **\$3,000,000** for a large-sized project (range **\$2,000,000 to \$4,000,000** with a budget period of up to 4 years).

The anticipated number of Collaborative Project awards is up to 5 in each size category type (small, medium and large categories).

There is a wide range of research needs that can be addressed by each Collaborative Project type. Applications must clearly identify which type of Collaborative Project (small, medium or large) is being proposed and provide sufficient supporting information to justify the type proposed. It is anticipated that Collaborative Projects of various types will be funded to achieve a suitable mix of projects that will advance HAI prevention research. Each Epicenter must propose to lead at least one Collaborative Project, and can propose up to three Collaborative Projects, with one Collaborative Project from each size category (small, medium or large).

All estimated funding amounts are subject to the availability of funds. Total amount awarded will also depend on the quality and cost of the applications received. The size of each award will vary depending on the nature and scope of the proposed research.

**Budget and Project Period.** The estimated total funding (direct and indirect) for the first 12-month budget period is **\$22,500,000** for up to 5 Core Projects plus up to 5 Collaborative Projects. The estimated total funding (direct and indirect) for the entire project period is **\$43,500,000** (Core plus Collaborative Projects). The Core project period will run from 07/01/2016-06/30/2020. Collaborative projects may have up to a two- to four-year project period, depending on the size of the project, within the Core project period.

#### **Application Research Strategy Length:**

- **Single Epicenter Core Projects:** The page limit for the Research Strategy section of the Research Plan for each Single Epicenter Core Project is 10 pages.
- **Multicenter Collaborative Projects:** The page limit for the Research Strategy section of the Research Plan for each Collaborative Project is 10 pages and is to be submitted by the Lead Epicenter. With contributions and assistance from each of the Participating Centers, the Lead Epicenter application should use these pages to describe the Collaborative Project(s) including the title, aims, and unique role for each Participating Epicenter involved in the project. (See additional information in Section I. 2 Approach)

**Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 are eligible to apply. In brief, the five awardees from CDC FOA CK11-001 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 in the eligible institutions/organizations listed in Section III.1 are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly.

**Number of PDs/Pis.** There will only be one PD/PI for each application. The PI must be the PI for the Core Project and must be the PI for the Lead Collaborating Project(s). If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.

**Number of Applications.** Each eligible institution/organization must submit one application that includes both the Single Epicenter Core Project and at least one (or up to three) Lead Collaborative Project(s).

**Special Date(s).** Not applicable.

**Application Materials.** See Section IV.1 for application materials. Please note that Form C is to be used when downloading the application package. [http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)

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

**Application Type.** New

**Additional Requirements:** Limited Eligibility Requirements must be met. Please see Part 2. Section III. for additional information.

## Part 2. Full Text

### Section I. Funding Opportunity Description

#### Statutory Authority

Public Health Service Act, Title 42, Section 243, 247b(k)(2).

#### 1. Background and Purpose

Healthcare-associated infections (HAIs) and other adverse events continue to cause significant morbidity and mortality among patients treated in U.S. healthcare institutions and add billions of dollars to healthcare costs. Recent advances in the understanding of the preventability of certain HAIs have been gained through activities designed to improve the implementation of existing recommendations for prevention practice in healthcare settings. It is anticipated that as existing recommendations continue to be more fully implemented, HAI rates will be further decreased. However, existing prevention strategies are limited and will not prevent all HAIs even when fully implemented. To improve upon recent gains in HAI prevention, and someday eliminate these infections, investments need to be made now to advance HAI prevention science.

The CDC Prevention Epicenters (PE) Program was established to develop, implement and evaluate the effectiveness of epidemiologically-based strategies to improve healthcare quality and patient safety. This FOA is designed to use the CDC Prevention Epicenters Program to translate basic, epidemiologic and technologic discoveries into new strategies for preventing HAIs, antimicrobial resistance (AR) and other adverse events in all types of healthcare facilities in the United States.

Prevention Epicenter (PE) research is based on five identified phases through which basic scientific discoveries are translated into improved population health, and these phases can be adapted to provide a framework within which to describe HAI prevention research needs. These phases of translational research include:

- 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 all HAIs, and many are unproven or not well-suited for a wide range healthcare settings and clinical situations. Therefore, there is a need for early translational research (e.g., Phases T0-T2) to expedite identification and development of additional effective prevention practices to enhance and improve HAI prevention across the spectrum of healthcare.

The research activities conducted under this funding opportunity announcement will be composed of two

mandatory categories of projects:

**1) Single Epicenter Core Projects:** One project proposed and carried out by a single applicant Epicenter to develop and test novel HAI prevention strategies that answer questions relevant to CDC's HAI Prevention Research Agenda.

**2) Multicenter Collaborative Projects:** At least one, or up to three, projects proposed by each applicant Epicenter to address issues that meet emerging or evolving HAI Prevention research needs and can best be addressed through multi-center studies.

### **Healthy People 2020 and other National Strategic Priorities**

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" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA supports "Healthy People 2020" priority areas HAI-1, reduce central-line associated blood stream infections (CLABSI), and HAI-2, reduce invasive healthcare-associated methicillin-resistant *Staphylococcus aureus* (MRSA) infections and is in alignment with the HHS Strategic Plan Goal 1, Objective B: Improve health care quality and patient safety, see <http://www.healthypeople.gov/2020/topics-objectives/topic/healthcare-associated-infections> and <http://www.hhs.gov/strategic-plan/goal1.html>

### **Public Health Impact**

Prevention of healthcare-associated infections is a focus of CDC's Winnable Battles Initiative. The Prevention Epicenter (PE) Program contributes to HAI prevention by fostering early innovation research that moves knowledge and discovery gained from the basic and epidemiologic sciences to its application in clinical and community settings. PE research focuses on identifying novel strategies for detection and prevention of HAIs and other adverse events such as post-surgical adverse events, bloodstream infections, *Clostridium difficile* infections, infections caused by antimicrobial-resistant organisms, and inappropriate antimicrobial use. The prevention gains resulting from Epicenter work reduce the morbidity, mortality, and costs associated with HAI.

### **Relevant Work**

- United States Department of Health and Human Services, Winnable Battles, Healthcare-associated Infections, Retrieved from <http://www.cdc.gov/winnablebattles/healthcareassociatedinfections/index.html>,
- United States Department of Health and Human Services, Healthy People 2020, Healthcare-associated Infections, Retrieved from <http://healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=17>
- United States Department of Health and Human Services, National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination, Retrieved from <http://www.hhs.gov/ash/initiatives/hai/infection.html>
- National Strategy for Combating Antibiotic Resistant Bacteria, September 2014. Retrieved from [http://www.whitehouse.gov/sites/default/files/docs/carb\\_national\\_strategy.pdf](http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf)
- Previous publications of the Prevention Epicenter Program can be found on CDC's Prevention Epicenter website <http://www.cdc.gov/HAI/epiCenters/index.html>.

### **Abbreviated list of recent Prevention Epicenter publications:**

- Knelson LP, Williams DA, Gergen MF, Rutala WA, Weber DJ, Sexton DJ, Anderson DJ on behalf of the Centers for Disease Control and Prevention Epicenters Program. A comparison of environmental contamination by patients infected or colonized with methicillin-resistant *Staphylococcus aureus* or vancomycin-resistant Enterococci: A Multicenter Study. Infect Control Hosp Epidemiol. 2014 Jul;35(7):872-5.

- Huang SS, Septimus E, Kleinman K, Moody J, Hickok J, Avery TR, Platt R for the CDC Prevention Epicenters Program and the AHRQ DECIDE Network and Healthcare-Associated Infections Program (2013). Targeted versus universal decolonization to prevent ICU infection. *New England Journal of Medicine*, 368:2255-2265.
- Climo MW, Yokoe DS, Warren DK, Perl TM, Bolon M, Herwaldt LA, Wong E. (2013). Effect of daily chlorhexidine bathing on hospital-acquired infection. *New England Journal of Medicine*, 368(6):533-42. Erratum in *New England Journal of Medicine* 2013; 368(24):2341.
- Lin MY, Lyles-Banks RD, Lolans K, Hines DW, Spear JB, Petrak R, Trick WE, Weinstein RA, Hayden MK, for the Centers for Disease Control and Prevention Epicenters Program (2013). The Importance of Long-term Acute Care Hospitals in the Regional Epidemiology of Klebsiella pneumoniae Carbapenemase- Producing Enterobacteriaceae. *Clinical Infectious Disease*, 57(9):1246-1252.
- Klompas M, Anderson D, Trick W, Babcock H, Kerlin MP, Li L, Sinkowitz-Cochran R, Ely EW, Jernigan J, Magill S, Lyles R, O'Neil C, Kitch BT, Arrington E, Balas MC, Kleinman K, Bruce C, Lankiewicz J, Murphy MV, E Cox C, Lautenbach E, Sexton D, Fraser V, Weinstein RA, Platt R; CDC Prevention Epicenters. The preventability of ventilator-associated events. The CDC Prevention Epicenters Wake Up and Breathe Collaborative. *Am J Respir Crit Care Med* 2015 Feb;191(3):292-301.

## 2. Approach

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

### Objectives/Outcomes

Prevention Epicenters nationwide identify and validate novel interventions that involve new translation of epidemiologic, technologic, or basic science observations into effective HAI prevention strategies. The investigators of the Prevention Epicenters eligible to apply to this FOA have collaborated with CDC in the past as a consortium to address emerging or evolving public health research needs related to the prevention of HAIs, AR and other adverse healthcare-associated events.

Each eligible institution/organization must submit one application that includes a Single Epicenter Core Project and one to three Multicenter Collaborative Projects.

### Single Epicenter Core Projects:

The Research Strategy section of the Research Plan for the Single Epicenter Core Project is limited to 10 pages. Applicants' research plan(s) should address activities they will conduct over the entire four-year project period.

The Research Objectives for the Single Epicenter Core Projects are:

- The development of a four-year research program designed to develop and test novel prevention strategies that answer questions relevant to CDC's HAI Prevention Research Agenda. The applications should emphasize early innovation research activities in phases T1 (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).
- The development of a plan to maintain ongoing collaboration between scientists with T0 expertise and those with T1/T2 expertise within the Epicenter. 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.
- The development of research focused on prevention of one or more healthcare-associated infections, including those prioritized in the HHS Action Plan to Prevent Healthcare-Associated Infections (e.g., device and procedure-associated infection, infections associated with *Clostridium difficile*, and methicillin-resistant *Staphylococcus aureus* [MRSA], and other MDROs, viral, and other pathogens).

For more information on the HHS Action Plan visit <http://www.hhs.gov/ophs/initiatives/hai/infection.html>.

The anticipated outcome of the proposed research will result in evidence for novel interventions that are mature enough to merit advancement through further T2 study.

Examples of research topics that might be considered for the Single Epicenter Core Projects include, but are not limited to, the following areas:

- T0 or T1 studies that may help identify candidate interventions for prevention and control of antimicrobial resistant bacterial or fungal pathogens in healthcare settings. Specific examples include, but are not limited to, carbapenem-resistant Enterobacteriaceae, methicillin-resistant *Staphylococcus aureus*, multidrug-resistant Acinetobacter, organisms carrying extended spectrum beta lactamases, azole-resistant Candida spp., and *Clostridium difficile*.
- Improving the understanding of the major determinants of healthcare-associated transmission of infectious pathogens (viral or bacterial) that can be modified for prevention and early T1 testing of interventions.
- Improving the understanding of the transmission determinants related to contamination of the healthcare environment that can be modified for prevention and early T1 testing of interventions.
- T0 or early T1 HAI Prevention research in non-hospital settings of interest (i.e., outpatient centers, independent dialysis centers, and long-term care facilities, including interventions that take into consideration the risk of inter-facility transmission among networks of facilities that share patients).
- Protecting the health of the microbiome as a means of preventing healthcare-associated transmission of bacterial pathogens.
- Other T0 or early T1 work on innovative strategies for preventing healthcare-associated infections.

### **Multicenter Collaborative Projects:**

Each applicant Epicenter must propose to lead at least one Collaborative Project, and can propose up to three Collaborative Projects, with one Collaborative Project from each size category (small, medium or large).

Any and all Collaborative Projects must be submitted with the initial Core Project application to be reviewed, scored and ranked. No Collaborative Projects can be proposed later during the four-year Core Project period.

The Research Strategy section of the Research Plan for each Collaborative Project is limited to 10 pages to be submitted by the Lead Epicenter. With contributions and assistance from each of the Participating Centers, the Lead Epicenter should use these pages to describe the Collaborative Project(s) including the title, aims, and unique role for each Participating Epicenter involved in the project. Applicants' research plan(s) should address activities they will conduct over the entire two- to four-year project period.

Two-year Collaborative Projects may begin in the first, second or third year of the Core Project period; three-year Collaborative Projects may begin in the first or second year of the Core Project period; and four-year Collaborative Projects must begin in the first year of the Core Project period. All Collaborative Projects must be proposed at the time of Core Project application submission.

The Research Objectives for the Collaborative Projects are:

- Development of a multicenter HAI prevention research project that includes 3 to 5 Epicenters that are eligible to apply for this FOA. One Epicenter will serve as the Lead and up to four Participating Epicenters may collaborate on the project.
- The development of research focused on prevention of healthcare-associated infections.
- Collaborative projects will typically involve research transitional phases late T1 and T2 and will meet emerging or evolving HAI Prevention research needs and involve multiple epicenters.
- Considerable planning to develop studies and delineate roles between eligible Epicenters is expected.

The anticipated outcome of the proposed research will be T2 evidence that is sufficient to warrant either

inclusion in CDC HAI prevention recommendations or investment in additional T2 confirmatory clinical studies.

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

- Late T1 or T2 studies of promising candidate interventions for prevention and control of antimicrobial resistant bacterial or fungal pathogens in healthcare settings. Specific examples include, but are not limited to, carbapenem-resistant Enterobacteriaceae, methicillin-resistant *Staphylococcus aureus*, multidrug-resistant Acinetobacter, organisms carrying extended spectrum beta lactamases, azole-resistant Candida spp., and *Clostridium difficile*.
- T2 studies of interventions focusing on decontamination of the healthcare environment as a means of preventing healthcare-associated infections and transmission of pathogens.
- T2 HAI Prevention research in non-hospital settings of interest (i.e., outpatient centers, independent dialysis centers, and long term care facilities, including interventions that take into consideration the risk of inter-facility transmission among networks of facilities that share patients.
- In some cases, multicenter collaborative work may be appropriate and preferable for certain T0 or T1 research questions that support development of innovative strategies for preventing healthcare-associated infections.

### **Additional budget instructions for Collaborative Projects:**

**1) Leading a Collaborative Project:** Each Lead Epicenter may propose a collaboration with up to four (4) Participating Epicenters for a given Collaborative Project. A budget separate from the Single Epicenter Core Project budget is needed for each Collaborative Project. The budget for such a project will be submitted by the Lead Epicenter and will clearly delineate the amount(s) needed for the Lead Epicenter from the amount(s) needed for the Participating Epicenter(s). The Participating Epicenters must be clearly named and their unique role clearly outlined in the Research Strategy section of the Research Plan proposed for the Collaborative Project.

**2) Participating in a Collaborative Project as a Non-Lead:** Each Epicenter may participate in up to **twelve (12)** (not including projects for which they are the Lead) Multicenter Collaborative Projects led by another Epicenter. When proposing to be a participating site, the Participating Epicenter will clearly reference the title and aims of the Lead Collaborative Project, and identify its own unique role in the project by submitting up to two pages to be included/incorporated into the Lead Epicenter's Research Strategy section of the Research Plan. The Participating Epicenter's budget for the Collaborative Project will be reflected in the Lead Epicenter's application and budget.

### **Target Population**

Research activities proposed under this announcement are required to target populations at risk for Healthcare-Associated Infections (HAIs) such as patients admitted to hospitals and long-term care facilities, as well as patients receiving care in ambulatory settings.

### **Collaboration/Partnerships**

Awardees of this FOA will be organized into a consortium. Principal Investigators from each of the awarded Epicenters from this FOA and CDC Project Officers will act as consortium representatives on the Epicenter Steering Committee. The steering committee will work collaboratively to serve in an advisory role to individual investigators as needed. A well-developed Program Steering Committee is integral to the program's success.

### **Evaluation/Performance Measurement**

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

The applicants should outline an evaluation plan in the application that includes the following:

- 1) Participation in the Prevention Epicenter Consortium which is overseen by the Epicenters Program Steering Committee. This includes, but is not limited to, active participation in conference calls, webinars, and in-person meetings (i.e., grantee meetings and special projects meetings).
- 2) Participation in projects that take advantage of the combined expertise and diversity of the Prevention Epicenters in order to advance research or adoption of an HAI-related innovation.
- 3) Progress toward completion of proposed research projects that can be feasibly completed within the four-year project period.
- 4) Development of peer-reviewed articles that report on proposed research projects.
- 5) Presentation of findings as a result of the proposed research project at meetings and conferences.

As part of each **Collaborative Project**, the Lead Epicenter PI should include measurable goals and aims based on the proposed research project period (two to four years). All of the same parameters regarding evaluation and performance measurement for the Core Project should be applied to the Collaborative Projects and be included as part of the Collaborative Project description.

### **Translation Plan**

The anticipated outcome of the proposed research should result in evidence for novel interventions that are mature enough to merit either inclusion in CDC HAI prevention recommendations or investment in large confirmatory clinical studies. The application will provide a plan for presentation of research findings at appropriate scientific meetings, and for publication in peer-reviewed literature. In addition, relevant findings will be made available to policy makers and, as appropriate, to federal advisory committees, including the Healthcare Infection Control Advisory Committee, and other entities and professional organizations that produce recommendations for HAI prevention. Relevant findings will be made available to agencies that support T3 research designed to translate T2 evidence into practice.

## **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:** \$43,500,000

**Estimated total funding available for the first year: \$22,500,000**

**Estimated total funding available for the entire project period: \$43,500,000**

Estimated funds available annually per awardee for Core Projects: \$500,000

Individual award ceiling for Core Projects: \$500,000

Individual award floor for Core Projects: \$400,000

Estimated funds available per Collaborative Project: **\$300,000 - \$4,000,000.**

Because Collaborative Projects may span 2-4 years, the estimated funds available annually per awardee may vary.

Individual award ceiling for Collaborative Projects: **\$4,000,000**

Individual award floor for Collaborative Projects: **\$300,000**

**The total average individual award for the first 12-month budget period may range from \$500,000 (if only the Core Project is awarded) to \$7,200,000 (if the Core and three Collaborative Projects are awarded).**

**The floor for a total individual award for the first 12-month budget period may range from \$400,000 (if only the Core Project is awarded) to \$1,300,000 (if the Core and three Collaborative Projects are awarded).**

**The ceiling for a total individual award for the first 12-month budget period may range from \$500,000 (if only the Core Project is awarded) to \$7,200,000 (if the Core and three Collaborative Projects are awarded).**

**Anticipated Number of Awards: 5**

Anticipated number of Core Project awards: up to 5

Anticipated number of Collaborative Project awards: up to 5 in each size category (small, medium and large)

**The ceiling and floor amounts listed below are for Core Projects only.**

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

**Award Ceiling:** \$500,000 Per Budget Period

**Award Floor:** \$400,000 Per Budget Period

**Total Project Period Length:** 4 year(s)

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

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

### Section III. Eligibility Information

#### 1. Eligible Applicants

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

Additional Eligibility Category:

#### 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

Additional Information on Eligibility:

Only the awardees of CDC FOA CK11-001 are eligible to apply.

- Harvard Pilgrim Healthcare Inc.
- Duke University
- Washington University
- University of Pennsylvania
- Hektoen Institute for Medical Research

See "Justification for Less than Maximum Competition" section of this FOA.

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

#### 4. Justification for Less than Maximum Competition

CDC has a need to emphasize collaborative, multi-site research projects in this FOA in order to obtain the best return on invested research dollars. To optimize quality and efficiency of the projects and to assure that the objectives are met, CDC plans to utilize the infrastructure and collaborative ties that were created through the activities of FOA CK11-001. Therefore, this FOA will be limited to the awardees of FOA CK11-001 for the following reasons:

1. CDC expects applicants to use the collaborative infrastructure created through FOA CK11-001. The time and money saved by utilizing the existing infrastructure can be invested in implementation of studies, increasing the size and impact of studies, as well as ensuring on-time completion of projects. Examples of existing collaborative infrastructure that can be built upon include:

a) An electronic data sharing network/database created and used by the awardees of FOA CK11-001.

b) Multicenter IRB agreements and arrangements that are currently in place for awardees of FOA CK11-001 that can be updated for new projects.

c) A network of multiple healthcare facilities that have demonstrated the ability and willingness to collaboratively participate in HAI prevention research, collect necessary health information to determine relevant clinical outcomes and process of care measures related to those outcomes, and that:

i. have an existing capacity for electronic healthcare recordkeeping and/or electronic clinical and laboratory data exchanges;

ii. include at least five acute care hospitals that participate in the National Healthcare Safety Network (NHSN);

iii. have demonstrated prior success in multi-facility collaboration in HAI prevention research;

iv. have established administrative capacity to coordinate and standardize intervention and data collection strategies across a large number of facilities representing the full 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).

2. This FOA has a shorter than usual project period for the Prevention Epicenters Program. Limiting eligibility to the five sites from FOA CK11-001 that have already established infrastructure will compensate for the time that would be needed to build infrastructure for collaborative projects by new awardees and would allow projects to be completed on time.

In summary, the awardees of FOA CK11-001 have collaboratively developed a research coalition and infrastructure that is optimally conducive to performing a wide variety of potential studies that evaluate the impact of interventions to prevent healthcare-associated infections, have a highly effective track record, and have already created an infrastructure that is necessary for the studies. Using these research funds to select a new group of investigators would jeopardize the likelihood of successful on time completion of projects and result in considerable excess expense due to the excess time and expense of developing such an infrastructure de novo among a group of new investigators. Therefore, competition is limited to the group of investigators awarded in FOA CK11-001.

**Justifications for increasing the funding ceiling and total funding amount:**

**a. To maximize collaborations, each Epicenter can now participate in as many as 12 collaborative projects (versus 4 in the previously published FOA CK16-004);**

**b. Appropriations for Antimicrobial Resistance research was recently obtained to provide more funds in this subtopic area;**

**c. As each collaborative project can now have as many as one lead plus four participating centers, extra funds are needed to compensate for the indirect costs for each participating center's subaward so that the lead center would have sufficient funds in the direct cost category for research purposes.**

## 5. Responsiveness

Not applicable

## 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%20for%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](http://Grants.gov)
- [eRA Commons](http://eRA Commons)

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

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

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

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

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

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

### 9. Cost Sharing

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

## 10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed. Each eligible institution/organization must submit one application that includes both the Single Epicenter Core Project and at least one (or up to three) Lead Collaborative Project(s) as part of the 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](http://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](mailto:pgotim@cdc.gov) for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide ([http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)),

except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional.

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

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

### 3. Letter of Intent

Due Date for Letter of Intent: **12/15/2015**

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 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 for the core and each collaborative project

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

**The letter of intent should be sent to:**

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: [GAnderson@cdc.gov](mailto: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](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](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.

**Throughout the application, text pertaining to the Core Project should be titled to begin with the words “Core Project” to distinguish it from the Collaborative Projects and text pertaining to the Collaborative Projects should be titled to begin with the size of the project and the words “Collaborative Project” (e.g., “Large Collaborative Project: Project Title”; “Medium Collaborative Project: Project Title”; “Small Collaborative Project: Project Title”).**

**The Lead Epicenter only needs to submit one SF424 for the Core and all proposed Collaborative Projects; however, the budget and budget justifications need to be listed separately for the Core Project and for each Collaborative Project.**

## 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 10 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](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) (<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](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](mailto:support@grants.gov)). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; [pgotim@cdc.gov](mailto: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](mailto: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: **01/15/2016**

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

## 10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review ([http:// www. whitehouse.gov/ omb/ grants spo](http://www.whitehouse.gov/omb/grants_spo)).

## 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 the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

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

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at <http://www.phe.gov/s3/dualuse>, for a comprehensive listing of those requirements.

Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future US Government (USG) funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

## 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](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/ElectronicReceipt/avoiding\\_errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm) or [http://grants.nih.gov/grants/ElectronicReceipt/submit\\_app.htm](http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm)

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

## Section V. Application Review Information

### 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<http://www.cdc.gov/about/organization/mission.htm>), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

### Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

#### Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

## 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 surveillance, outbreak investigation and epidemiologic study of adverse events in healthcare settings? Does the application include a plan to maintain ongoing interdisciplinary collaboration between scientists with this expertise and those developing novel candidate interventions, performing efficacy testing and developing evidence-based guidelines for healthcare over the entire two- to four-year project period? Have the investigators documented a significant track record of publication in the area of healthcare infection control and healthcare epidemiology?

### **Additional Investigator(s) Criterion for Collaborative Projects:**

Have the investigators demonstrated success in multi-center collaborative projects in the past?

## 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 surveillance, outbreak investigation and epidemiologic discoveries) into application of candidate HAI prevention interventions 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 application describe a process for overcoming barriers that might arise from gaining IRB approval for all of the facilities that are eligible and willing to collaboratively participate in HAI prevention research as part of this award?

Does the application include metrics for assessing goals for the entire funding period and approximate timelines for the entire two- to four-year project period? Does the application include appropriate power calculations?

### **Additional Approach Criteria for Collaborative Projects:**

Does the application describe a credible and feasible strategy for coordinating the work among multiple participating centers? Does the application describe a strategy for sharing data among multiple centers?

## 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 application described an infrastructure that is conducive to performing a wide variety of potential studies that evaluate the impact of interventions to prevent healthcare-associated infections?

### **Additional Environment Criteria for Collaborative Projects:**

Does the application provide documentation that all Participating Epicenters are committed and capable of completing the study? Does the Lead Epicenter application provide evidence of demonstrated ability to lead and coordinate research that involves multiple healthcare facilities?

## **2. Additional Review Criteria**

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

### **Biohazards**

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

As part of the Biohazards assessment, reviewers will evaluate whether the research proposed qualifies as Dual Use Research of Concern. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called “dual use research.” Dual use research of concern is a subset of dual use research defined as: “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.” The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

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

## **2. Additional Review Criteria**

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

### **Protections for Human Subjects**

If the research involves human subjects but does not involve one of the six categories of research that are exempt under [45 CFR Part 46](#), the committee will evaluate the justification for involvement of

human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements ([http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm#ar1](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](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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150)).

### **Biohazards**

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

## **3. Additional Review Considerations**

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

### **Resource Sharing Plans**

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/grants/additionalrequirements/index.html>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and

reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

#### **4. Review and Selection Process**

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

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- If insufficient funds are available, the diversity of research focus areas may be considered in making funding recommendations; also, if insufficient funds are available, Epicenters may be limited to leading only one or no Collaborative Project.

As part of the initial scientific merit review, Single Epicenter Core Projects will be scored and ranked separately from the Multicenter Collaborative Projects. Single Epicenter Core Projects must receive Overall Impact scores between 10 and 60 and must be recommended for funding to be eligible to be awarded a Lead Collaborative Project. Collaborative Projects must also score between 10 and 60 to be awarded. Collaborative Projects will be ranked separately in each of the three categories of small, medium and large. Thus, one application may receive up to four scores for the projects proposed. The following algorithm will be used in determining funding preferences for Multicenter Collaborative Projects when funds are limited:

- First, the best scoring Collaborative Project in the large category will be given funding preference.
- Second, the best scoring Collaborative Project in the medium category will be given funding preference. If an application with the best scoring project in the medium category has already received funding preference in the large category, then the 2nd best scoring project in the medium category will be selected, and so forth.
- Third, the best scoring Collaborative Project in the small category will be given funding preference. If an application with the best scoring project in the small category has already received funding preference in the large or medium category, then the 2nd best scoring project in the small category will be selected, and so forth.

#### **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](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](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:

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 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

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

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

[AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR](#)

[AR-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”](#),  
[October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR 32 –; FY 2012 Enacted General Provisions](#)

The following are additional policy requirements relevant to this FOA:

### **Dual Use Research of Concern (DURC)**

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

The DURC policy applies to recipients in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy. This policy also applies to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Research funded by CDC involving these agents or toxins must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review may be completed by an Institutional Review Entity (IRE) identified by the funded institution. Many institutions task their Institutional Biosafety Committees with this responsibility.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or cooperative agreement plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. For example, CDC may request that the institution periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal. CDC’s Institutional Biosecurity Board (IBB) is responsible for approval of all DURC risk mitigation plans. The award recipient is responsible for adhering to the risk mitigation plan, as approved by CDC.

### **3. Additional Policy Requirements**

The following are additional policy requirements relevant to this FOA:

#### **HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications**

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by

Congress. For more information, visit the HHS website at: [http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol memo.html](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) ([http:// www.usaspending. gov/](http://www.usaspending.gov/)). For the full text of the requirements, please review the following website: [https:// www.frs.gov/](https://www.frs.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](http://www.plainlanguage.gov/pLLaw/index.cfm).

### **Tobacco and Nutrition Policies**

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

#### **Tobacco:**

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

#### **Nutrition:**

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:
  - [http://www.gsa.gov/graphics/pbs/ Guidelines\\_for\\_Federal\\_Concessions\\_and\\_Vending\\_Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf)
  - [http://www.cdc.gov/ nccdphp/dnpao/hwi/toolkits/ tobacco/index.htm](http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm)
  - <http://www.cdc.gov/nutrition/index.html>

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

## **4. Cooperative Agreement Terms and Conditions of Award**

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations 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; the CDC Project Officer is 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:

- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Collaborating with other Epicenter investigators in developing and implementing multicenter Collaborative Projects.
- Conducting a four-year research program designed to develop and test novel prevention strategies related to the prevention of HAIs.
- Ensuring that each program year budget includes costs for travel to support one to two staff (i.e., the Principal Investigator, a Co-Investigator or Project Manager) to attend four, 2-day planning and steering meetings over the four-year Core Project period in Atlanta, Georgia with CDC staff and other cooperative agreement awardees.
- Actively participating, as a member of the Epicenters' Steering Committee. This includes, attending annual grantee meetings in Atlanta convened by CDC staff, and participation in regular communication with other members of the steering committee through regular teleconferences (potentially weekly).
- Ensuring high quality data collection, quality assurance, and quality control procedures are in place for epidemiological and laboratory data.
- Communicating with the CDC Project/ Science Officers about research progress, budgetary changes, and upcoming deadlines for ethical review and abstract submission for international conferences.
- The PI/PD will allow adequate time for CDC clearance of all publications/presentations.
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaging in the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

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

- Providing training for project staff on technical and biosafety issues.
- Participating in data analysis, interpretation of results, dissemination and publication of results, if CDC contribution so merits.
- Carrying out continuous review of all activities to ensure project objectives are being met.
- Attending committee meetings and participating in conference calls for the purposes of assessing overall progress, and for program evaluation purposes.
- 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.
- Assisting in the development of research protocols for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.
- Serving as an advisor to the Epicenters Program Steering Committee.
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

Areas of Joint Responsibilities include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all institutions participating in the project and for OMB-PRA review, if needed.

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

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

## 5. Reporting

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.fsrc.gov](http://www.fsrc.gov) on all subawards over \$25,000. See the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hsgps107.pdf>) for additional information on this reporting requirement.

## A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, [www.grants.gov](http://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](http://grants.nih.gov/grants/forms.htm). For further information, contact [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov). Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

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

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: <http://era.nih.gov/commons/>. Organizations not yet registered can go to [https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp](https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp) for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: [http:// era.nih.gov/ commons /index.cfm](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](mailto: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](mailto: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](mailto:PGOTIM@cdc.gov)

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

### Scientific/Research Contact(s)

Amy Yang, PhD

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8836

Fax: 404-718-8822

Email: [vdz9@cdc.gov](mailto:vdz9@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](mailto:GAnderson@cdc.gov)

**Financial/Grants Management Contact(s)**

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**Section VIII. Other Information**

Other CDC funding opportunity announcements can be found at [www.grants.gov](http://www.grants.gov).  
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

**Authority and Regulations**

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.  
Public Health Service Act, Title 42, Section 243, 247b(k)(2).