

Centers for Disease Control

National Center for Immunization and Respiratory Diseases Extramural Research Program Office

Improving HPV Vaccination Coverage Among Adolescent Patients: A Randomized Controlled Trial of AFIX and Remote Physician-to-Physician Engagement Strategies

RFA-IP-17-002

Application Due Date: 02/07/2017

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Immunization and Respiratory Diseases Extramural Research Program Office (NCIRD ERPO)
National Center for Immunization and Respiratory Diseases (NCIRD)

Funding Opportunity Announcement (FOA) Title

Improving HPV Vaccination Coverage Among Adolescent Patients: A Randomized Controlled Trial of AFIX and Remote Physician-to-Physician Engagement Strategies

Activity Code

Cooperative Agreement – Research Project (U01)

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-IP-17-002

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

93.083
93.185

Category of Funding Activity:

Health

FOA Purpose

This funding opportunity announcement (FOA) will support a factorial design randomized controlled trial (RCT) to evaluate the effectiveness of Assessment, Feedback, Incentives, eXchange (AFIX) and remote Physician-to-Physician (P2P) vaccine provider engagement strategies to increase adolescent human papillomavirus (HPV) vaccination rates and monitor the impact of immunization service delivery of other adolescent vaccines, i.e., tetanus-diphtheria-acellular pertussis (Tdap), meningococcal conjugate (MenACWY), and influenza (Flu), by vaccine providers serving the Vaccines for Children (VFC) program in one or more state, local and territorial public health jurisdictions.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-IP-17-002, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**01/10/2017**
Application Due Date:	**02/07/2017**

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: **03/15/2017**

Secondary Review: **04/11/2017**

Estimated Start Date: **07/01/2017**

Expiration Date: **02/08/2017**

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

Required Application Instructions

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

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

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

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

Executive Summary

- **Purpose:** This funding opportunity announcement (FOA) will support a factorial design randomized controlled trial (RCT) to evaluate the effectiveness of Assessment, Feedback, Incentives, eXchange (AFIX) and remote Physician-to-Physician (P2P) vaccine provider engagement strategies to increase adolescent human papillomavirus (HPV) vaccination rates and monitor the impact of immunization service delivery of other adolescent vaccines, i.e., tetanus-diphtheria-acellular pertussis (Tdap), meningococcal conjugate (MenACWY), and influenza (Flu), by vaccine providers serving the Vaccines for Children (VFC) program in one or more state, local and territorial public health jurisdictions.
- **Mechanism of Support:** Research Project - Cooperative Agreement (U01).
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire 3-year project period is $1,500,000. The anticipated number of awards is 1. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of the award may also vary.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $500,000. The estimated total funding (direct and indirect) for the entire project period is $1,500,000. The project period is anticipated to run from 7/1/2017 to 6/30/2020.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 of this announcement are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills,

knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE:CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

- **Number of PDs/PIs.** There will only be one PD/PI for each application. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.
- **Number of Applications.** Eligible applicant institutions may submit only one application.
- **Application Type.** New.
- **Special Date(s).** A conference call with potential applicants will be held on **Tuesday, December 13, 2016 at 12:00 noon ET.** Phone Number: 1-866-662-8986, Passcode: 8378091.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Sections 317 [42 U.S.C. 247b (k)(1)] and 318 [42 U.S.C. 247c], as amended.

1. Background and Purpose

The U.S. Advisory Committee on Immunization Practices (ACIP) provides annual vaccination recommendations and guidance to the Secretary of the Department of Health and Human Services, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) regarding strategies and progress toward meeting the national immunization program goals for control of vaccine-preventable diseases. Under authority of the Immunization Act, and through the operation of the Vaccines for Children (VFC) and 317 Immunization Programs, the federal government advances public health immunization capacity by providing federal assistance to U.S. states and, in consultation with state health authorities, to political subdivisions of states, other public entities, and U.S. territories (hereafter referred to as state, local and territorial immunization program partners or immunization program partners). This assistance is to address urgent needs, sustain public delivery systems, and provide funds for purchase of vaccines. The VFC Program allows eligible infants, children and adolescents to receive ACIP-recommended vaccines from VFC-enrolled vaccine providers at no cost. Additionally, Immunization Program funding supports activities to build immunization capacity, to improve immunization service delivery, and to integrate and track immunization data through Immunization Information Systems (IISs)(e.g., immunization registries in state, local and territorial Immunization Program jurisdictions). Quality improvement strategies, such as the Assessment, Feedback, Incentives, eXchange (AFIX) Program, are implemented with vaccine providers in the state, local and territorial jurisdictions to improve service delivery by identifying low immunization rates, improving immunization delivery practices, and ensuring that vaccine providers are:

- Aware of, and knowledgeable about, their immunization rates and missed opportunities to vaccinate;
- Motivated to incorporate changes to their current practices;
- Ready to try new immunization service strategies; and
- Capable of sustaining these new behaviors.

AFIX is used routinely to increase vaccination rates and improve service delivery by vaccine providers. AFIX allows public health practitioners and VFC-enrolled providers to review vaccination coverage and delivery

data, discuss and implement quality improvement strategies, address provider-specific barriers, and offer information and materials to provider staff on various topics, such as reducing missed vaccination opportunities or discussing human papilloma virus (HPV) vaccination with parents. Despite steady gains toward meeting immunization guidelines for adolescent vaccine targets, HPV vaccination coverage levels are below levels reported for other vaccine-preventable diseases.

About 79 million Americans are currently infected with HPV and an estimated 14 million more persons are infected each year; half of these infections occur in persons 15-24 years of age. Of the more than 40 types of HPV that can infect humans, a small subset cause cervical cancer and other less common cancers. Each year in the United States, there are about 17,500 women and 9,300 men affected by cancers related to HPV; many of these cancers could be prevented with HPV vaccination.

HPV vaccination coverage levels in the United States are far lower than coverage levels for other adolescent vaccines. In 2014, among adolescents aged 13–17 years, 87.6% had received ≥ 1 tetanus-diphtheria-acellular pertussis (Tdap) vaccine dose, and 79.3% had received ≥ 1 meningococcal conjugate vaccine (MenACWY) dose. However, only 60.0% and 41.7% of adolescent females and males, respectively, had received ≥ 1 HPV vaccine dose and only 39.7% and 21.6% had received ≥ 3 HPV doses, respectively. These coverage levels fall dramatically short of the Healthy People 2020 3-dose HPV vaccination coverage goal of 80% for female and male adolescents; this underscores the need for more effective public health interventions that can decrease missed opportunities for immunization and target the barriers to optimal vaccination coverage.

Consequently, this FOA seeks to evaluate the effectiveness of two engagement strategies, AFIX and remote Physician-to-Physician (P2P), either alone or in combination, to increase HPV vaccination rates through improved immunization service delivery by VFC-enrolled vaccine providers in one or more state, local or territorial immunization program jurisdictions.

AFIX has been deployed historically to strengthen childhood immunization programs, despite the fact that the effectiveness of assessment and feedback components of the AFIX program have been empirically demonstrated in studies of childhood and adult vaccination programs. Adolescent-focused AFIX is underutilized relative to childhood-focused AFIX. CDC recommends that state and local public health communities increase their use of adolescent-focused AFIX. This, along with CDC's interest in fostering the development, implementation, and evaluation of existing and novel HPV vaccination strategies, reflects a commitment to accelerate the pace of improvements to HPV vaccination coverage levels among U.S. adolescents.

AFIX is a four-step, quality improvement program implemented by state, local and territorial immunization program partners to improve standards of practice and immunization service delivery levels by public or private vaccine provider offices enrolled in the Vaccines for Children Program.

1. **Assessment**: Qualitative and quantitative data is collected on vaccine providers, including vaccination coverage, services, knowledge, attitudes, behaviors, and records management, to identify and understand factors that may affect vaccination coverage at the provider level.
2. **Feedback**: Observations and results from the Assessment step are discussed with the vaccine provider and input for ways to improve the immunization delivery system in the practice is shared. Results from this step are used to develop a "Quality Improvement Action Plan" with S.M.A.R.T. (Specific, Measurable, Achievable, Realistic, and Time-bound) objectives.
3. **Incentives:** State, local and territorial immunization program partners explore various options to motivate vaccine providers to strengthen or implement new immunization delivery strategies and, ultimately, improve vaccination coverage levels. Incentives are generally used in combination with educational materials used during the Feedback step.
4. **eXchange**: Following Assessment and Feedback (usually 3 to 6 months), state, local and territorial immunization program partners monitor progress made by vaccine providers toward implementing the Quality Improvement Action Plan and provide additional support, if needed or requested. The eXchange step allows the public health staff to evaluate whether providers have the necessary resources

and information to improve the quality of their immunization services.

Most AFIX program visits are conducted by non-physicians working for or with the public health department. Although exceptions exist, most AFIX visits include little or no participation from provider physicians.

Physician recommendation is known to be an important predictor of HPV vaccination rates among adolescents. However, many physicians providing HPV vaccine, especially pediatricians, may not routinely see the medical outcomes of unvaccinated patients who develop HPV-related cancers. Therefore, some of these physicians may not fully appreciate the benefits of strict adherence to HPV vaccination guidelines. Physician-to-physician (P2P) engagement is a strategy used to provide education, guidance, and support to these physicians. P2P engagement in support of HPV vaccination commonly takes the form of an office visit or a lecture.

Some state, local or territorial public health departments have incorporated P2P office visits into their AFIX program, providing in-person P2P engagement during the review and discussion of the provider's performance. Limited evidence suggests that this strategy is appreciated by provider physicians and may be effective in increasing HPV vaccination coverage. In-person, physician-led AFIX engagement would likely be prohibitively expensive and, therefore, unsustainable for the majority of state, local or territorial public health departments. An alternative strategy would be to use telephone (or webinar) engagement between a provider physician and a physician working for or with the health department (remote P2P). Remote P2P engagement is a strategy that can be implemented independently for providers not receiving an AFIX visit, or incorporated as an enhancement to routine AFIX site visits. If effective, remote P2P engagement may provide a cost-effective and sustainable way for a large number of state, local or territorial public health departments to reach adolescent vaccine providers in their jurisdictions to assess, promote, and support HPV vaccination efforts.

Healthy People 2020 and other National Strategic Priorities

This FOA directly supports the following Healthy People 2020 focus areas:

- IID-11.4- IID-11.5 Increase coverage level of 3 doses of human papillomavirus (HPV) vaccine for females and males.
- IID-17.1- IID-17.2 Increase the percentage of public and private health providers with coverage levels among children measured within the past year.

Public Health Impact

This FOA supports research that addresses the gap in data measuring the effect of assessment and feedback on adolescent vaccination coverage rates by investigating two strategies for vaccine provider engagement: AFIX and remote P2P. Both engagement strategies will emphasize provider assessment and feedback, and both target vaccine providers that are enrolled in VFC program immunization delivery service to adolescents. Valuable information for HPV vaccination coverage improvement and program budgeting should result from interpretation of study data measuring the effectiveness and costs of each intervention study arm.

This FOA supports CDC's National Center for Immunization and Respiratory Diseases performance goals that will:

- Develop and expand the impact of VFC provider engagement programs, streamline work with providers on improving immunization standards of practices, improve and sustain high vaccination coverage levels for children and adolescents, and reduce missed opportunities to vaccinate.
- Increase national public awareness and provider knowledge about vaccine-preventable diseases and immunization recommendations using an array of media and culturally-appropriate tools and resources to support informed decision-making about vaccination.
- Improve methods to assess vaccination rates across the lifespan in order to identify groups at risk for vaccine-preventable diseases, monitor racial and ethnic disparities in vaccination coverage, evaluate the effectiveness of programs designed to increase coverage levels, monitor uptake of new vaccines, assess

differential impact of vaccine shortages, measure performance by various types of providers, and provide greater understanding of socio-demographic and attitudinal factors associated with vaccination.

Relevant Work

1. Vaccines for Children (VFC) Immunization Program Partner Contacts. http://www.cdc.gov/vaccines/programs/vfc/contacts-state.html
2. Reagan-Steiner S *et al*. 2015. National, regional, state, and selected local area vaccination coverage among adolescents aged 13-17 years—;United States, 2014. MMWR Morb Mortal Wkly Rep. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a3.htm.
3. CDC AFIX website. http://www.cdc.gov/vaccines/programs/afix/index.html. [This site provides detailed information on AFIX, its components, and resources used by awardees, including the AFIX Policies and Procedures Guide, the AFIX Site Visit Questionnaire form, and frequently asked questions.]
4. AFIX Policies and Procedures Guide. https://www.cdc.gov/vaccines/programs/afix/downloads/standards-guide.pdf.
5. Community Preventive Services Task Force. The Community Guide: Increasing appropriate vaccination—provider assessment and feedback. http://www.thecommunityguide.org/vaccines/RRproviderassessment.html.
6. Gargano LM, Herbert NL, Painter JE, *et al*. 2013. Impact of a physician recommendation and parental immunization attitudes on receipt or intention to receive adolescent vaccines. *Hum Vacc Immunother*. 9(12):2623–2633.
7. Healthy People 2020. Immunization and infectious diseases—objectives. https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives.
8. Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook - 13th Edition (2015) http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

2. Approach

A factorial design randomized controlled trial (RCT), as outlined in this funding opportunity announcement, provides a resource-efficient experimental design to compare the effectiveness of AFIX and P2P provider engagement strategies to increase HPV vaccination coverage levels and improve immunization service delivery by VFC-enrolled providers in state, local and territorial public health jurisdictions. Both engagement strategies emphasize the use of assessment and feedback interactions to improve immunization service delivery. Information gained from this study will contribute valuable information on mechanisms for application and potential costs for implementing new engagement strategies in other state and local public health communities.

Under this study design, applicant organizations will conduct or partner with one or more public health Immunization Program Partners to accomplish the research study objectives. The target audience for the trial will be VFC-enrolled vaccine providers from state, local or territorial jurisdictions that administer the VFC Program (Immunization Program Partners) and for which non-physician, in-person AFIX is standard procedure. All providers included in the study are required to be VFC-enrolled providers that administer vaccines to adolescents. Each provider will be randomly assigned to one study arm.

Application research plans must include, at minimum, a 2 x 2 factorial study design, including all of the four study arms identified below and in Table 1 and Figure 1. Additional data collection and study time intervals may be proposed, if feasible, within the proposed budget. Other methods of follow-up may also be proposed, depending on the site's resources, experience, and capabilities.

Table 1. Study design requirements.

Study arm	Intervention strategy	
	In-person AFIX	Remote P2P engagement
Control	–	–
1	+	–
2	–	+
3	+	+

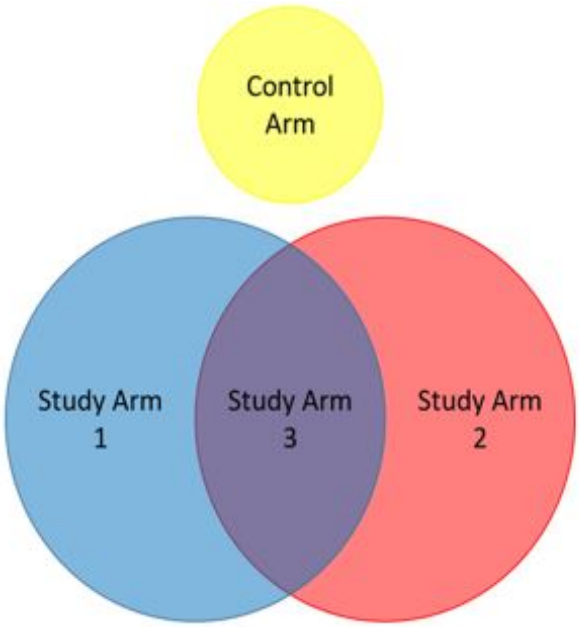


Figure 1. Schematic of interventions. The study includes in-person AFIX (Study Arms 1, 3) and remote P2P engagement (Study Arms 2, 3). The Control Arm has no interventions.

Study Arms

1. Control Arm: No Vaccine Provider Intervention

Initial vaccination coverage (t_0), and missed opportunity data for control providers, will be queried from the public health jurisdiction's Immunization Information System (IIS). Follow-up IIS queries will be conducted 6, 12, and 18 months later (t_6, t_{12}, t_{18}). Study organizers should ensure that initial IIS queries of control providers are temporally dispersed and not all performed at the start of the study. Vaccine providers assigned to the Control Arm should not receive any AFIX visits or other adolescent vaccine interventions from the beginning of the study period until at least 18 months (t_{18}) following the provider's initial IIS query.

2. Study Arm 1: In-Person AFIX

CDC's AFIX Policies and Procedures Guide (See Part 2, Section 1.1, Relevant Work) recommends the inclusion of an in-person site visit. This recommendation is nearly universally implemented. Though exceptions exist, the site visit is typically conducted by a non-physician, working for or with a health department, with little or no participation from the vaccine provider physician(s). The eXchange step may be completed in person, as well.

The following conditions should be met to satisfy the requirements of Study Arm 1:

- AFIX visits performed during the study period should be "routine", i.e., the AFIX visits should proceed as they would have proceeded in the absence of a research study.

Specifically:

- The awardee or public health jurisdiction partner should coordinate vaccine provider site visits.
- Adolescent-only and combined adolescent/childhood AFIX visits are acceptable for this arm.
- AFIX-only and combined VFC/AFIX site visits are acceptable.

- Exchange visits should be integrated into current standard procedures typically used by the awardee or the public health jurisdiction study partner. The AFIX procedures should be well described and documented in detail. The study's follow-up IIS queries (at 6, 12, and 18 months following the initial AFIX assessment) should take place on schedule, regardless of when the eXchange query is conducted.
- The AFIX visits conducted in this study arm should be counted as official AFIX visits for the public health jurisdiction. Data can be entered into the AFIX Online Tool and included in the AFIX Annual Report.

3. Study Arm 2: Remote P2P Engagement

Providers assigned to this study arm will not receive an in-person AFIX visit. They will instead receive assessment and feedback via remote P2P engagement. A consulting physician working for or with the participating public health department will call the provider physician(s) (the lead physician will be requested) at a previously scheduled and agreed upon time. Prior to the call, the consulting physician will review IIS query results of the provider's coverage levels and communicate the time intervals at which future queries will take place. The consulting physician will also provide HPV vaccine and HPV-related cancer education and discuss strategies to improve performance. Study organizers and the consulting physician(s) will have the opportunity to work with CDC experts to develop the specifics of the P2P messaging.

The following conditions should be met to satisfy the requirements of Study Arm 2:

- P2P engagement should be conducted remotely, by telephone or webinar. The intervention method used should be standardized.
- Remote P2P calls should be pre-scheduled at a time agreed upon between the consulting physician and the provider physician(s).
- Remote P2P engagement should include a consulting physician working for or with the health department and a provider physician (unless the provider does not have a physician on staff, in which case, the call should include the awardee or cooperating public health jurisdiction's consulting physician and the individual in charge of the practice).
- Vaccine coverage and missed opportunity assessment data from the IIS should be shared with the provider physician, along with any other materials (e.g., an immunization report card, fact sheets, or talking points for communicating with parents).
- P2P engagement sessions should cover a standardized list of topics to reduce call-to-call variation in core messages and discussion points.
- Individual providers assigned to Study Arm 2 should not receive any AFIX visits or other adolescent vaccine interventions from the beginning of the study period until at least 18 months following the provider's initial IIS query.

4. Study Arm 3: In-Person AFIX + Remote P2P Engagement

The procedures and requirements provided above for Study Arms 1 and 2 also apply to this study arm, with the following additions:

- Remote P2P engagement should be scheduled to occur within 2 weeks of the initial AFIX site visit.
- In addition to the standardized list of topics described for remote P2P engagement in Study Arm 2, the consulting physician will also give the provider physician a brief summary of the recent AFIX visit to the provider's office. This will require that the awardee or public health jurisdiction partner brief the consulting physician with a visit summary that includes IIS data and the strengths or weaknesses observed during the visit.
- The coverage and missed opportunity data from the recently conducted AFIX visit should be discussed during the remote P2P call. Because the data will be less than 2 weeks old, there will be no need to

conduct a fresh IIS query.

Immunization Information Systems (IIS) Data Queries

IIS query data will be used to assess provider-level adolescent vaccination performance. These data, in turn, will inform the content delivered to providers during feedback. Therefore, the following conditions should be met within the VFC Program jurisdiction to satisfy the study's IIS requirements:

- ≥ 75% of adolescent providers participate in IIS.
- ≥ 75% of adolescent children participate in IIS.
- ≥ 70% of doses are processed within 30 days of administration.

Cost Analysis

The objective of this FOA is to support research that investigates strategies incorporating assessment and feedback to increase adolescent HPV vaccination rates by cost-effective and sustainable means. The research plan should include a cost analysis plan for each study arm that includes factors such as salary for the consulting physician(s) and the development of tools (e.g., immunization report cards) or resources (e.g., guides for communicating with parents) to strengthen assessment and feedback in the study's intervention arms.

Additional Study Details

This study will yield results that are intended to be transferrable to the greater community of city, state and territorial public health jurisdictions. The following considerations are included to address this goal:

- The study should be conducted within one or more state, local or territorial public health jurisdiction(s). The jurisdiction must implement VFC Program services and have VFC-enrolled provider participation rates and sample numbers.
- Whenever possible, the study jurisdiction and the scope of vaccine provider service in that jurisdiction should include urban and rural settings.
- Research plans should include statistical justification for the sample sizes proposed.
- Applications must include a letter(s) of support from the participating public health organization(s) (See Section III.5, Responsiveness).
- When recruiting the consulting physician(s), study organizers should prioritize qualified physicians that are clinically active, or recently clinically active, and have experience caring for patients with HPV-related cancers (e.g., as a referring, diagnosing, or treating physician). This is because adolescent vaccine providers may be influenced more strongly by fellow clinicians that have seen the effects of HPV infections in adults.
- Ensure that the proposed budget, personnel, timeline, sample size, and other technical and logistic details are sufficient to complete the study objectives for all four required study arms. When planning implementation strategies, applicants are encouraged to focus on pragmatic methods that could be adopted and maintained widely across jurisdictions (e.g., cities, states, and territories).

Objectives/Outcomes

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

The objectives of this FOA are to support research that investigates assessment and feedback strategies to increase adolescent HPV vaccination rates and evaluates the cost-effectiveness of each strategy.

At a minimum, the study will address the following objectives:

- Quantify changes over time in HPV vaccination rates among adolescent patients at clinics receiving interventions involving adolescent AFIX and remote physician-to-physician (P2P) engagement strategies.
- Estimate the costs associated with the implementation and maintenance of each intervention type examined.
- Quantify concurrent changes in rates for other vaccines that are recommended for adolescents, e.g., tetanus-diphtheria-acellular pertussis vaccine (Tdap), meningococcal conjugate vaccine (MenACWY), and seasonal influenza vaccine (Flu).

The expected outcomes include:

- Increased HPV vaccination rates and decreased missed opportunities among adolescent patients served by providers receiving assessment and feedback via in-person AFIX (Study Arms 1 and 3).
- Increased HPV vaccination rates and decreased missed opportunities among adolescent patients served by providers receiving assessment and feedback via remote P2P engagement (Study Arms 2 and 3).
- Identification of the most cost-efficient assessment and feedback intervention strategy.
- Dissemination of study findings and conclusions via preparation of a manuscript describing study findings suitable for publication in a peer-reviewed journal.

Target Population

VFC-enrolled vaccine providers from state, local or territorial public health jurisdictions that vaccinate adolescents.

Collaboration/Partnerships

With few exceptions, applicant organizations will need to collaborate and partner with one or more of the 64 public health department jurisdictions that receive federal Immunization Program funding. This collaboration will establish a critical basis for the formal assessment of the AFIX and remote P2P strategies in increasing vaccination coverage levels for HPV in target populations of interest. Successful completion of this study is expected to lead to best practices for immunization improvement interventions that can be generalized to other city, state and territorial public health jurisdictions.

Evaluation/Performance Measurement

As part of the application, the PI should include measurable goals and aims based on a 3-year research project period. The grantee will establish specific, measurable, achievable, realistic and time-bound (SMART) project objectives for each activity described in the application's research plan, and develop and implement project performance measures that are based on specific programmatic objectives.

At minimum, the application should detail the following process and outcome measures:

Process Measures

Provide assessment and feedback via in-personAFIX visits (Study Arms 1 and 3).

- Measure: Number of in-person adolescent AFIX visits completed during the study period.
- Measure: Number and percentage of phone, webinar, and in-person eXchange visits conducted during the study period.

- Measure: Number of in-person adolescent AFIX visits reported via the AFIX Online Tool during the study period.

Provide assessment and feedback via remote P2P engagement (Study Arms 2 and 3).

- Measure: Number of remote P2P engagement sessions attempted to be scheduled with a provider physician during the study period.
- Measure: Number of remote P2P engagement sessions successfully scheduled with a provider physician during the study period.
- Measure: Number of remote P2P engagement sessions with a provider physician completed during the study period.
- Measure: Number of remote P2P engagement sessions canceled by a provider physician during the study period.
- Measure: Number of remote P2P engagement sessions skipped, but not canceled, by a provider physician during the study period.
- Measure: Number of remote P2P engagement sessions with a provider physician completed within two weeks of the AFIX site visit (Study Arm 2 only).
- Measure: Description of the remote P2P engagement calls or webinars, such as: duration, questions/issues raised by the provider physician, and receptivity of the provider physician to the session.

Outcome Measures

Quantify vaccine program performance changes (all study arms).

- Vaccination rates at all time points (t_0, t_6, t_{12}, t_{18}) for 1 HPV, 2 HPV, 3 HPV, and other adolescent vaccines, e.g., Tdap, MenACWY, Flu.
- Missed opportunities at all time points (t_0, t_6, t_{12}, t_{18}) for 1 HPV, 2 HPV, 3 HPV, and other adolescent vaccines, e.g., Tdap, MenACWY, Flu.
- Statistical analysis comparing the magnitude of change in vaccination rates across study arms for each vaccine dose.
- Statistical analysis comparing the magnitude of change in missed opportunities across study arms for each vaccine dose.

Perform cost-effectiveness analyses of assessment and feedback intervention strategies.

Translation Plan

The PI should describe how the findings from this study 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.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

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

Application Types Allowed:

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

Estimated Total Funding: $1,500,000

Year 1: $500,000

Year 2: $500,000

Year 3: $500,000

Estimated total funding available for first year, including direct and indirect costs: $500,000

Estimated total funding available for entire project period, including direct and indirect costs: $1,500,000

Anticipated Number of Awards: 1

The ceiling and floor amounts listed below are for individual awards for the first 12-month budget period.

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: $350,000 Per Budget Period

Total Project Period Length: 3 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

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

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

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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

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

Applications should include letters of support from research partner(s). Letters of support should include:

- Statement of partner's resources and commitment to the success of the study, including any skills or experiences that may make them uniquely qualified to serve as a study partner.
- Statement that the number of VFC-enrolled provider offices in the selected public health jurisdiction are adequate to complete the study with the sample sizes required.
- Acknowledgement that the public health jurisdiction's IIS includes ≥ 75% adolescent provider participation, ≥ 75% participation of adolescent children, and ≥ 70% vaccine processing within 30 days.

The letter should confirm understanding of the following study details and/or willingness to support the following study activities:

- The public health partner supports the proposed study and is willing to collaborate with the applicant.
- Individual providers assigned to the Control Arm and Study Arm 2 will not receive any AFIX visits or other public health partner-coordinated adolescent vaccine interventions from the beginning of the study period until at least 18 months following the initial provider IIS query of each provider's vaccination coverage levels and missed opportunities.
- The public health partner is willing and able to coordinate with the applicant to ensure that the specified number of in-person adolescent AFIX visits can be performed within the timeframe described in the research plan.
- The AFIX visits may count as official AFIX visits for the public health jurisdiction and will be entered into the AFIX Online Tool and included in the AFIX Annual Report.
- The public health partner is willing to collaborate with the consulting physician(s) recruited for the study, and the public health partner is willing to exchange information involving in-person AFIX visits. Specifically, the public health partner confirms that they will keep the consulting physician(s) informed of upcoming AFIX visits and will provide the consulting physician(s) with a visit summary that includes coverage and missed opportunity data from the IIS and an overview of strengths or weaknesses the consulting physician may wish to address during the remote P2P engagement.

6. Required Registrations

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

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.
All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.
Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

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

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

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@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/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf, except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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

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

3. Letter of Intent

Due Date for Letter of Intent: **01/10/2017**

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

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

Name of the Applicant

Descriptive title of proposed research

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

Names of other key personnel

Participating institutions

Number and title of this funding opportunity announcement

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.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 (R&R) 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 (R&R) Application Guide unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf must be followed along with any additional instructions provided in the FOA.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Please note the new requirement for a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application (see immediately above).

6. Appendix

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

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf.

9. Submission Dates & Times

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

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

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

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

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

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

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

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.

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

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

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

Due Date for Applications: **02/07/2017**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf .
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.
Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Awardees who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: http://www.cdc.gov/grants/additionalrequirements/index.html for revised AR-25.

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

2) The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

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

4) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

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

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

6) Please note the new requirement regarding the inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this FOA (http://www.cdc.gov/grants/additionalrequirements/index.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

12. Other Submission Requirements and Information

Application Submission

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

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

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

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding _errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

What is the potential or actual impact of the research on public health in the US?

Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?

If successful, do the research results have the potential to be scalable and reach a large portion of adolescents in the United States?

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 application demonstrate that the PD/PI has experience conducting and publishing academic health services delivery research that focuses on vaccination?

Does the application demonstrate that the PD/PI has a record of successful collaboration with public health organizations (e.g., state or territorial health departments)?

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?

Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to public health?

Does the proposed research offer innovative strategies, with reasonable potential to be scalable and sustainable across a variety of public health jurisdictions, to recruit physicians to work for or with the health department on the physician engagement activities described in the FOA?

If the application includes additional study arms beyond the four required study arms, do these study arms include innovative strategies, with reasonable potential to be scalable and sustainable across a variety of public health jurisdictions, to recruit physicians to work for or with the health department on physician engagement activities?

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 proposed study jurisdiction(s) target audience of VFC-enrolled vaccine providers serve urban and rural populations, if possible?

Does the application include an analytic plan with outputs and measures or metrics identified to assess the outcomes?

Does the application include sample size calculations demonstrating that the study design and sample sizes proposed will allow for differences between study arm performance measures to be realistically detected with statistical power?

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?

Does the project utilize critical partnerships/collaborations with at least one public health jurisdiction that administers VFC program services?

Does the project support key stakeholder involvement throughout the research process?

Have the PD/PIs provided a letter of support from the collaborating public health partner that demonstrates support for conducting the study in their jurisdiction?

Do letter(s) of support confirm that health department staff will support the conditions for each intervention study arm, including coordinating with study leaders and consulting physician(s)?

If the application includes plans to conduct the study with more than one public health partner jurisdiction, does the proposed research project, timeline, and budget appear to be adequate to accomplish this expansion?

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/grants/additionalrequirements/index.html).

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// www.cdc.gov /maso /Policy /policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

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

Dual Use Research of Concern

Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop

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

3. Additional Review Considerations

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

Please note the new requirement regarding the inclusion of a Data Management Plan (DMP) in applications described below under "Resource Sharing Plan(s)" and also in AR-25 in the Additional Requirements section of this FOA (http://www.cdc.gov/grants/additionalrequirements/index.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

Resource Sharing Plan(s)
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
New additional requirement: CDC requires awardees for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.
Investigators responding to this funding opportunity announcement should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.
The DMP should include, at a minimum, a description of the following:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

4. Review and Selection Process

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

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

- Will receive a written critique.

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

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC’s framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this funding opportunity announcement.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

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/sites/default/files/grants/grants/policies-regulations/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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-25: Data Management and Access

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 2015 Enacted General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/grants/additionalrequirements/index.html

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

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

Tobacco:

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

Nutrition:

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

- http://www.gsa.gov/graphics/pbs/ Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- http://www.cdc.gov/tobacco/basic_information/healthy_people/toolkit/index.htm
- http://www.cdc.gov/obesity/strategies/food-serv-guide.html

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

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

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

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance

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

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

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).
The AR-25 http://www.cdc.gov/grants/additionalrequirements/index.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the

project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- Developing materials and strategies for remote P2P engagement based on CDC-developed materials and guidance.
- Describing the in-person AFIX procedures and documenting the details of each in-person AFIX visit.
- Detailing a plan and process for working with CDC staff to develop and refine timelines, intervention protocols, study objectives, methods, and data collection instruments.
- Complying with the responsibilities for extramural investigators for the Data Management and Access Additional Requirement (AR-25) described at: http://www.cdc.gov/grants/additionalrequirements/index.html
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf).
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

- Providing technical assistance for the development of materials for remote P2P engagement.
- Providing support to the PI in the development and refinement of intervention protocols, study objectives, technical methods, and data collection instruments. CDC will also provide technical assistance on data analysis plans, revision of manuscripts, and other products resulting from this FOA, as warranted.
- Assisting the PI, as needed, in complying with the responsibilities for extramural investigators for the Data Management and Access Additional Requirement (AR-25) described at: http://www.cdc.gov/grants/additionalrequirements/index.html
- 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 Responsibility include:

None; all responsibilities are divided between awardees and CDC staff as described above.

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.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the

non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

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

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All

new submissions should be prepared and submitted as FFRs.
CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.
Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm
FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.•
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional

dissemination efforts that did or will result from the project.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

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

Scientific/Research Contact

Deborah Loveys, PhD

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: 404-718-8834

Fax: 404-718-8822

Email: dloveys@cdc.gov

Peer Review Contact

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Centers for Disease Control and Prevention
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Financial/Grants Management Contact

Edna Green
Office of Financial Resources
Office of Grant Services
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U.S. Department of Health and Human Services
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Fax: (770) 488-8350
Email: EGreen@cdc.gov

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Public Health Service Act, Sections 317 [42 U.S.C. 247b (k)(1)] and 318 [42 U.S.C. 247c], as amended.