

Centers for Disease Control and Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office

Increase Access to Care for Black Men Who Have Sex with Men

RFA-PS-16-004

Application Due Date: 02/12/2016

Increase Access to Care for Black Men Who Have Sex with Men

RFA-PS-16-004

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Extramural Research Program Office (NCHHSTP ERPO)
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Funding Opportunity Announcement (FOA) Title

Increase Access to Care for Black Men Who Have Sex with Men

Activity Code

U01 Research Project Cooperative Agreements

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-PS-16-004

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

93.941

Category of Funding Activity:

Health

FOA Purpose

The goals of this FOA are to design and implement an in-person assistance intervention and to evaluate the effects of the intervention on insurance uptake, insurance coverage, and rates of linkage to, and retention in, HIV-related health care and other associated health services among black MSM age 18 or older; intervention cost-benefit will also be assessed.

Key Dates

Publication Date: **To receive notification of any changes to RFA-PS-16-004, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: **01/07/2016**

Application Due Date: **02/12/2016**

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

Scientific Merit Review: **04/26/2016**

Secondary Review: **05/25/2016**

Estimated Start Date: **08/31/2016**

Expiration Date: **02/13/2016**

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

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose.** The goals of this FOA are to design and implement an in-person assistance intervention and to evaluate the effects of the intervention on insurance uptake, insurance coverage, and rates of linkage to, and retention in, HIV-related health care and other associated health services among black MSM age 18 or older; intervention cost-benefit will also be assessed.
- **Mechanism of Support.** Cooperative agreement.
- **Funds Available and Anticipated Number of Awards.** The estimated total funding available is up to $400,000 for the first 12-month budget period and up to $1,500,000 for the entire project period of three (3) years. The anticipated number of awards is one. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $400,000. Estimated funding for the second and third years is $600,000 and $500,000, respectively. The estimated total funding (direct and indirect) for the entire project period is $1,500,000. The project period will run from 08/31/2016 to 8/30/2019.
- **Application Research Strategy Length.** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement. For this FOA, the page limit for the Research Strategy section of the Research Plan is 25 pages.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III.1 are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** There will only be one PD/PI per application. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.
- **Number of Applications.** Eligible applicant institutions may submit only one application.
- **Application Type.** New.
- **Special Date(s).** A conference call with all potential applicants will be held on Tuesday, January 5,

2016 at 12:00 noon Eastern Time. Phone Number: 1-866-662-8986; Passcode: 8378091.

- **Application Materials.** See Section IV.1 for application materials. Please note that Form C is to be used when downloading the application package. http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Sections 301 and 318 of the Public Health Service Act (42 U.S.C. Sections 241 and 247c), as amended.

1. Background and Purpose

In 2010, men who have sex with men (MSM) accounted for 78% of new HIV infections among males and 63% of all new infections. Even though African Americans comprise only 12% of the US population, black MSM almost matched white MSM in numbers of new HIV infections (10,600 and 11,200, respectively)(1). Black MSM face obstacles to seeking preventive or medical care and following through with referrals or appointments, such as costs and lack of health insurance due to unemployment, under-employment, or low literacy skills that impede use of insurance websites (2,3). Recent studies found that approximately 40% of black MSM are uninsured or had a lapse in health insurance coverage in the previous 12 months (3,4). The fact that HIV-infected black MSM have positive health outcomes once they become engaged in care argues for the cost-effectiveness of removing obstacles to access (5,6). An intervention to help black MSM, especially young black MSM, overcome socioeconomic obstacles to health care can improve the health and health care seeking of all black MSM, regardless of their HIV status, and can prevent transmission and acquisition of HIV among at-risk black MSM. Although the focus of this FOA is on black MSM, especially young black MSM, other racial and ethnic groups will not be denied access to services.

Under this FOA, applicant organizations will implement a structural intervention to remove an obstacle to health care access: lack of health insurance. Applicant organizations will implement and evaluate provision of an in-person assistance intervention to help black MSM clients, age 18 and older, regardless of their HIV status, to enroll as policy holders in health insurance or Medicaid according to the Patient Protection and Affordable Care Act (ACA) at the end of their HIV testing session (7). The intervention aligns with the Office of Management and Budget's (OMB's) emphasis on application of behavioral insights (8,9). Behavioral insights are used to restructure the context in which health-related decision-making occurs in order to promote the selection of beneficial options. Enrollment assistance changes choice context by improving the convenience of the enrollment process, reducing anxiety about making mistakes, providing guidance on choice of insurance plans, and reducing clients' time costs, because health insurance enrollment is combined with another activity (HIV testing).

The goals of this FOA are to design and implement an in-person assistance intervention and to evaluate the effects of the intervention on insurance uptake, insurance coverage, and rates of linkage to, and retention in, HIV-related health care (i.e., HIV treatment, Pre-exposure Prophylaxis [PrEP]) and other associated health services (e.g., mental health counseling, substance use treatment) among black MSM age 18 or older. Intervention cost-benefit will also be assessed.

Specifically, the project will explore whether providing in-person assistance to enroll in health insurance or Medicaid following HIV testing will: 1) increase the proportion of black MSM who obtain health insurance; 2) result in better health outcomes among clients; 3) improve the linkage and retention rates of black MSM, especially those diagnosed with HIV; and 4) increase linkage and retention rates sufficiently to justify the cost of implementing the intervention (cost-benefit analysis). Analyses will be used to assess the efficacy of

the intervention as an emerging practice. During an HIV testing event, all black MSM clients will receive services that include, but are not limited to, an HIV test and test results, referral to needed psychosocial services, and enrollment in health insurance or Medicaid, if needed. Black MSM clients who test positive for HIV will also receive linkage to HIV care services, patient navigation, and partner services according to local protocols. The certified Centers for Medicare and Medicaid Services (CMS) navigator or certified application counselor (CAC) who provides the enrollment assistance, or a colleague accompanying that person, will be the person administering the HIV test.

References:

1. HIV in the United States: At A Glance. Accessed November 25, 2014 from http://wwwdev.cdc.gov/hiv/statistics/basics/ataglance.html

2. Millett GA, *et al*. Comparisons of disparities and risks of HIV infection in black and other men who have sex with men in Canada, UK, and USA: a meta-analysis. Lancet 2012; 380(9839):341-348.

3. Sullivan PS, *et al*. Explaining racial disparities in HIV incidence in black and white men who have sex with men in Atlanta, GA: a prospective observational cohort study. Annals of Epidemiology 2015; 25(6):445-454.

4. Hall G, *et al*. A Comparison of referred sexual partners to their community recruited counterparts in The BROTHERS Project (HPTN 061). AIDS Behav. 2015 Feb 11.

5. Moving Black MSM Along the HIV Care Continuum webinar. Accessed August 16, 2014 from http://www.aids.gov/pdf/bmsm-webinar-06252014.pdf.

6. Turning the Tide on HIV, Division of HIV/AIDS Prevention Annual Report 2013. Accessed August 16, 2014 from http://www.cdc.gov/hiv/pdf/policies_dhap_annualreport_2013.pdf.

7. In-Person Assistance in the Health Insurance Marketplaces, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight. Accessed November 24, 2014 from http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/assistance.html.

8. OMB Memorandum M-13-17: Next Steps in the Evidence and Innovation Agenda. July 2013 from http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-17.pdf. Accessed November 25, 2014.

9. Bettinger EP, *et al*. The role of application assistance and information in college decisions: results from the H&R Block FAFSA experiment. The Quarterly Journal of Economics 2012; 127(3):1205-1242.

10. Recommendations for HIV prevention with adults and adolescents with HIV in the United States, 2014. Accessed May 4, 2015 from http://stacks.cdc.gov/view/cdc/26062.

Health Equity:

The program supports efforts to improve the health of populations disproportionately affected by HIV/AIDS, viral hepatitis, sexually transmitted diseases (STDs) and TB by maximizing the health impact of public health services, reducing disease prevalence, and promoting health equity consistent with the National HIV/AIDS Strategy available at https://www.whitehouse.gov/administration/eop/onap/nhas.

Health disparity is a particular type of health difference that is closely linked with social or economic disadvantage based on racial or ethnic group, religion, socioeconomic status, gender, mental health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or other characteristics historically linked to discrimination or exclusion [HP 2020 - http://www.healthypeople.gov/2010/hp2020/advisory/PhaseI/glossary.htm]. Health disparities in HIV, viral hepatitis, STDs, and TB are inextricably linked to a complex blend of social determinants that influence which populations are most severely affected by these diseases.

Social determinants are the economic and social conditions that influence the health of individuals, communities and jurisdictions and include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion.

Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic disadvantage. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after particular health disparities are eliminated.

Programs should use data, including social determinants data, to identify communities within their jurisdiction that are disproportionately affected by HIV, viral hepatitis, STDs and TB and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, programs should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions that are tailored for the communities for which they are intended.

Healthy People 2020 and other National Strategic Priorities

This FOA aligns with the National HIV/AIDS Strategy goals (http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf):

- Reducing new HIV infections
- Increasing access to care and improve health outcomes for people living with HIV
- Reducing HIV-related health disparities

This announcement also supports several Healthy People 2020 (HP2020) objectives. The HP2020 objectives supported by this announcement include:

- HIV-6: Reduce new AIDS cases among adolescent and adult men who have sex with men
- HIV-13: Increase the proportion of persons living with HIV who know their serostatus
- HIV-19: Increase the proportion of persons who are linked to HIV medical care within 3 months of HIV diagnosis
- HIV-20: Increase the proportion of persons with an HIV diagnosis who had at least one HIV medical care visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits
- HIV-21: Increase the proportion of persons with an HIV diagnosis in medical care who were prescribed antiretroviral therapy for the treatment of HIV infection at any time in the 12-month measurement period
- HIV-22: Increase the proportion of persons with an HIV diagnosis in medical care with a viral load <200 copies/mL at the last test during the 12-month measurement period

This FOA aligns with OMB's emphasis on the application of behavioral insights (https://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-17.pdf) and has the potential to identify a scalable, structural-level intervention for black MSM and contribute to reducing HIV infection among this population.

Finally, CDC has identified HIV prevention as a winnable battle. This FOA aligns very closely with the 3 key strategies of CDC's HIV winnable battle effort (http://www.cdc.gov/winnablebattles/hiv/index.html):

- Intensify HIV prevention efforts in communities where HIV is most heavily concentrated
- Expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches for persons living with HIV and those at high risk of infection
- Maximize the proportion of people with HIV who have suppressed viral load by improving diagnosis, linkage and retention in care, and antiretroviral provision and adherence

Additional strategic priorities:

1. CDC Division of HIV/AIDS Prevention (DHAP) Strategic Plan: http://www.cdc.gov/hiv/pdf/policies_DHAP-strategic-plan.pdf
2. Executive Order (July 15, 2013): www.whitehouse.gov/the-press-office/2013/07/15/executive-order-hiv-care-continuum-initiative
3. Minority AIDS Initiative (MAI): http://www.hhs.gov/ash/ohaidp/initiatives/
4. Affordable Care Act: http://aids.gov/federal-resources/policies/health-care-reform
5. Standards for Privacy of Individually Identifiable Health Information: http://privacyruleandresearch.nih.gov/

Public Health Impact

In 2010, men who have sex with men (MSM) accounted for 78% of new HIV infections among males and 63% of all new infections. Even though blacks comprise only 12% of the US population, black MSM nearly equal white MSM in numbers of new HIV infections (10,600 and 11,200, respectively). HIV-infected black MSM have positive health outcomes once they become engaged in care; however, black MSM face obstacles to accessing preventive or medical care or following through with referrals or appointments, such as costs and lack of health insurance due to unemployment, under-employment, or low literacy skills that impede use of insurance websites.

This FOA will evaluate an intervention to help black MSM, especially young black MSM, overcome socioeconomic obstacles to accessing health care which can improve the health and health care-seeking of black MSM, regardless of their HIV status, and can prevent transmission and acquisition of HIV among at-risk black MSM. The intervention will be an in-person enrollment assistance, following HIV testing, to help black MSM obtain health insurance or Medicaid. Intervention effects on insurance uptake, insurance coverage, and rates of linkage to, and retention in, HIV-related health care (i.e., HIV treatment, PrEP) and other associated health services (e.g., mental health counseling, substance use treatment) will be assessed. If demonstrated to be efficacious, the intervention can be quickly adopted by organizations that provide HIV testing targeted to black MSM.

Relevant Work

1. Bettinger EP, *et al*. The role of application assistance and information in college decisions: results from the H&R Block FAFSA experiment. The Quarterly Journal of Economics. 2012;127(3): 1205-1242.

2. Blankenship KM, Bray SJ, Merson MH. Structural interventions in public health. AIDS. 2000; 14 (Suppl. 1):11-21.

3. Centers for Disease Control and Prevention. (2011). High-Impact HIV Prevention: CDC's Approach to Reducing HIV Infections in the United States. Accessed May 1, 2015 from http://www.cdc.gov/hiv/strategy/dhap/pdf/nhas_booklet.pdf

4. Freeman JD, Kadiyala S, Bell JF, Martin DP. The causal effect of health insurance on utilization and outcomes in adults: a systematic review of US studies. Medical Care 2008; 46(10):1023-32.

5. Frieden TR. A framework for public health action: The health impact pyramid. Am J Public Health. 2010; 100(4):590-595.

6. In-Person Assistance in the Health Insurance Marketplaces, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight. Accessed November 24, 2014 from http://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/assistance.html.

7. Millett GA, *et al*. Comparisons of disparities and risks of HIV infection in black and other men who have sex with men in Canada, UK, and USA: a meta-analysis. Lancet 2012; 380(9839):341-348.

8. Moving Black MSM Along the HIV Care Continuum webinar. Accessed August 16, 2014 from http

://www.aids.gov/pdf/bmsm-webinar-06252014.pdf.

9. Office of National AIDS Policy. National HIV/AIDS Strategy for the United States [Report] July 2010. Accessed April 20, 2015 from https://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf.

10. OMB Memorandum M-13-17: Next Steps in the Evidence and Innovation Agenda. July 2013. Accessed November 25, 2014 from http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-17.pdf.

11. Thornton JA, Rice JL. Does extending health insurance coverage to the uninsured improve population health outcomes? Appl Health Econ and Health Policy 2008; 6(4):217-30.

12. Turning the Tide on HIV, Division of HIV/AIDS Prevention Annual Report 2013. Accessed August 16, 2014 from http://www.cdc.gov/hiv/pdf/policies_dhap_annualreport_2013.pdf.

13. Wejnert, Cyprian, et al. HIV infection and awareness among men who have sex with men–20 cities, United States, 2008 and 2011.PloS One 8.10 (2013): e76878.

2. Approach

Applications submitted in response to this FOA should:

- Propose partnering with more than one type of community-based organization (CBO) to demonstrate the ability to evaluate different ways to implement the intervention.
- Include a detailed description of the applicant's and partner organizations' access to, or plan for gaining access to, black MSM at high risk for acquiring or transmitting HIV for purposes of the research project.
- Include a detailed description of the applicant's and partner organizations' ability to recruit sufficient numbers of the target population for proposed research activities.

Objectives/Outcomes

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

Investigators will design, implement and evaluate provision of an in-person assistance intervention to help black MSM clients enroll as policy holders in health insurance or Medicaid, according to the Patient Protection and Affordable Care Act (ACA), at the end of their HIV testing session, regardless of their HIV status. The goals of the FOA are to evaluate the effects of the intervention on insurance uptake, insurance coverage, and rates of linkage to and retention in HIV-related health care (i.e., HIV treatment, PrEP) and other associated health services (e.g., mental health counseling, substance use treatment). Intervention cost-benefit will also be assessed. CDC will coordinate with the Centers for Medicare and Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) to assist awardees in planning, developing, implementing, and evaluating the intervention.

Analyses will be used to assess the efficacy of the intervention as an emerging practice.

During an HIV test event, all black MSM clients will receive services that include, but are not limited to, an HIV test and test results, referral to needed psychosocial services, and enrollment in health insurance or Medicaid, if needed. Black MSM clients who test positive for HIV infection will also receive linkage to care services, patient navigation, and partner services according to local protocols. The certified CMS navigator or certified application counselor (CAC) who provides the enrollment assistance or a colleague accompanying that person will be the person administering the HIV test.

During the course of this study, investigators will be expected to:

- Obtain Institutional Review Board (IRB) and Office of Management and Budget (OMB) approvals for the data collection and analyses.
- Perform HIV testing targeting black MSM according to local protocols, including providing referral to

psychosocial services, linkage to health care services, patient navigation, and partner services.

- Integrate the intervention into targeted HIV testing programs during marketplace insurance open enrollment months (November 1-January 31).
- Employ or acquire lap-top computers to enroll clients during fixed location and mobile outreach HIV testing.
- Partner with Community-Based Organizations (CBOs) to implement the in-person enrollment assistance intervention using either certified CMS navigators or CACs. Navigators and CACs can be in-house staff, obtained from a CMS Navigator grantee, or who are (CBO) staff trained with project funds. The number of these staff members should be appropriate for the workload of the proposed intervention activity.
- Have a procedure in place to refer all study ineligible persons, regardless of race or ethnicity, to services consistent with local standards of care, e.g., existing healthcare services and insurance enrollment assistance.
- Offer the in-person health insurance enrollment assistance intervention to all black MSM during marketplace open enrollment months, unless they are covered by their parents' health insurance.
- Collect data on black MSM clients receiving an HIV test when marketplace insurance enrollment is open (intervention condition). These data will include health insurance status, insurance enrollment decision (and why), source of insurance (Medicaid or Marketplace) acquired through the intervention, choice of change of insurance plan (and why), and housing status. Additional health outcomes may be proposed, especially outcomes whose measures are in existing administrative datasets. For black MSM clients who are referred to HIV-related health care or HIV-associated health services, also collect data on linkage to and retention or reengagement in that care or service.
- Integrate provision of publically available information on health insurance enrollment into targeted HIV testing programs during months when marketplace insurance enrollment is closed (February 1-October 31). Information should not mention the grantee's provision of the intervention.
- Collect data on black MSM clients receiving an HIV test when marketplace insurance enrollment is closed (comparison condition). These data will include health insurance status and housing status. Additional health outcomes may be proposed, especially outcomes whose measures are in existing administrative datasets. For black MSM clients who are referred to HIV-related health care or HIV-associated health services, data should also be collected on linkage to, and retention or reengagement in, that care or service.
- Not provide in-person assistance with Medicaid enrollment during months when marketplace insurance enrollment is closed.
- Collect data on each CBO's integration of the intervention and protocols, number of staff receiving navigator or application counselor certification, and costs associated with implementing the in-person enrollment assistance intervention.
- Conduct quality assurance activities and process evaluation studies with partner sites and CBOs.

During the course of the FOA project period, it is expected that investigators will align research activities to the following schedule and timeline:

- **Year 1**: Establish a Memorandum of Understanding (MOU) with partnering organizations; develop and submit a comprehensive protocol for local and CDC IRBs, and other reviews and approvals as needed (such as OMB); acquire lap-top computers; pilot assessment instruments to be used for the research project; get CBO staff trained as CACs, as needed;
- **Year 2**: Implement the intervention during open enrollment months; conduct evaluation of participants in treatment and comparison conditions, conduct follow-up assessments;
- **Year 3**: Implement the intervention during open enrollment months; conduct evaluation of participants in treatment and comparison conditions; complete remaining follow-up assessments; conduct data cleaning and data analyses; disseminate the findings.

A sample project timeline is described in Figure 1 below.

FIGURE 1: SAMPLE PROJECT TIMELINE USING AN INSTITUTIONAL CYCLE DESIGN

	YEAR 1												YEAR 2												YEAR 3											
	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
	Obtain OMB and IRB approvals																																			
s1													B	B			O			O						O										
s2															B	B	B			O			O						O							
s3																				B	B	B			O			O					O			
s4																											B	B	B			O			O	

B = baseline observation months

O = follow-up observation months

= cyclic intervention event (in-person health insurance enrollment assistance) months

Sample follow-up observation points: For participants referred to HIV-related health care (i.e., HIV treatment, PrEP) in each sample:

1. Linkage to HIV-related health care within 3 months
2. Completion of at least one HIV-related health care visit within 6 months
3. Completion of at least two HIV-related health care visits within 12 months

Note: Each row (N=4) represents a separate cohort. The two cohorts from marketplace open enrollment months (s2, s4) can be combined for analysis. The two cohorts from months during which marketplace insurance enrollment is closed (s1, s3) can be combined for analysis.

In order to accomplish the objectives and meet the goals of the FOA, investigators should include detailed procedures for the research design, implementation of the intervention for black MSM, the collection of quality assurance, process, and outcome data, and analysis of outcomes, including criteria for assessing strength of the evidence of intervention effect, in their research plan proposal.

To meet published design criteria for evidence-based interventions for improving participation in HIV care as described by the CDC (http://www.cdc.gov/hiv/prevention/research/compendium/lrc/bestpractices.html), the proposed research plan should include the following study elements:

Criteria for Study Design:

- Prospective or quasi-prospective study design.
- Appropriate and concurrent comparison arm, or appropriate non-concurrent comparison arm that was implemented in a different clinic or agency within 12 months of the start of the intervention and was similar with respect to population and setting.
- Random allocation of participants to study arms or if non-randomization, potential bias in allocation to intervention is minimized.

The study is amenable to evaluation using an Institutional Cycle design as described in Figure 2, below.

FIGURE 2: BASIC INSTITUTIONAL CYCLE DESIGN

O_{s1}	O_{s1}								
		X	O_{s2}	O_{s2}					
					O_{s3}	O_{s3}			
							X	O_{s4}	O_{s4}

----------TIME---------->

O = observation events of the same groups

sX = number of the different samples that are used

X = cyclic intervention events

Intervention Implementation Benchmarks:

- For *linkage to care* interventions, linkage to care occurs within or less than 6 months after the initiation of the intervention.
- For *retention in care* interventions, retention in care occurs at least 6 months after the initial care visit.

Quality Assurance Plan:

The application's research plan should describe procedures for collection and analysis of quality assurance measures and application of findings to ensure that the insurance enrollment intervention is delivered with fidelity by well-trained and qualified staff, including, but not limited to:

- Guidance for the implementation of the intervention for black MSM during the study period, including recruitment and retention of new participants.
- Procedures to prevent confounding between study conditions.
- A logic model that specifies intervention components or activities and the outcomes expected for each component.

Process Evaluation Data:

The application's research plan should describe procedures for collection and analysis of process evaluation data to understand the implementation of in-person health insurance enrollment assistance following HIV testing. Process evaluation data will include, but may not be limited to:

- Types and characteristics of partner CBOs implementing the intervention
- Source(s) of the CMS navigators or CACs who enroll the clients
- Characteristics of the CMS navigators or CACs
- Characteristics of study period HIV testing events
- Number of black MSM who are offered HIV tests and the number who accept testing
- Number of black MSM participating at each HIV testing event who have no health insurance
- Number of black MSM who accept testing who are offered insurance enrollment assistance and the number who accept assistance
- Characteristics of black MSM who are offered in-person health insurance enrollment assistance
- Insurance enrollment decision and reason(s) for the decision

- Change of insurance plan decision and reason(s) for the decision
- Numbers and types of referrals given
- Participants' perceptions of and reactions to the intervention activities and services provided
- Resources used to deliver the intervention (including basic costs associated with delivering the intervention)
- Modifications made to the intervention implementation procedures

Outcome Evaluation Data:

Collection and analysis of the following outcome evaluation data from at least 400 black MSM during treatment months and at least 400 black MSM during comparison months:

- Number of black MSM who are successfully enrolled for the first time
- Number of black MSM who change their insurance plan
- Number of newly-enrolled black MSM who enroll in Medicaid and number who enroll in private insurance through the Marketplace
- Number of black MSM who enroll or change plans through the Marketplace who enroll in bronze level of coverage, number who enroll in silver, and number who enroll in gold or platinum
- For participants referred to HIV-related care (i.e., HIV medical care, PrEP)
    - Length of time between when the first completed HIV-related care visit (linkage) occurred and when the study period HIV test was performed
    - Length of time between when subsequent HIV-related care visits (retention) occurred and when the study period HIV test was performed
    - Percent who completed at least one HIV-related medical visit after their study period HIV test was performed
    - Percent who completed at least 2 HIV-related medical visits within 12 months after their study period HIV test was performed
- For participants referred to HIV-associated health services (e.g., mental health counseling, substance use treatment)
    - Length of time between when the first completed HIV-associated health service visit (e.g., initial assessment) occurred and when the study period HIV test was performed
    - Length of time between when subsequent HIV-associated health service visits (e.g., entry into withdrawal or recovery program) occurred and when the study period HIV test was performed
    - Additional HIV-associated health outcomes, with appropriate measures may be proposed
- For participants with previously-diagnosed HIV infection and who were never in HIV care
    - Length of time between when first positive test for HIV infection occurred and when the study period HIV test was performed
    - Length of time between when the first completed HIV medical visit (linkage to care) occurred and when the study period HIV test was performed
- For participants with previously-diagnosed HIV infection and who had left HIV care
    - Length of time between their most recent HIV medical visit and when the study period HIV test was performed
    - Length of time between when the next completed HIV medical visit (reengagement in care) occurred and when the study period HIV test was performed

Criteria for Analysis of Outcomes:

- Analysis of participants in study arms as originally allocated, or contaminated participants may be excluded if numbers are small, but participants may not be re-assigned for analytic purposes
- Analysis of participants may be based on intervention exposure, where participants exposed to < 50%

of the entire intended intervention may be excluded
- Analysis must be based on between-group comparisons on post-intervention levels or on pre-post changes in measures
    - For pre-post changes used in analysis, measures must be identical, including identical recall period
- Analysis based on a 2-sided test with a p value ≤ 0.05
- With non-randomized assignment, either no statistical differences exist in baseline levels of the outcome measure, or baseline differences must be controlled for in the analysis. If moderately biased assignment or historical comparison was used, differences in baseline demographics also must be controlled for in the analysis
- Baseline sample of ≥ 40 participants (or charts) per study arm

Criteria for Assessing Strength of Evidence of Intervention Effect:

- Statistically significant ($p \leq 0.05$) positive intervention effect for ≥ 1 relevant outcome measure
    - A positive intervention effect is defined as an improvement in linking to, retention in, or re-engagement in HIV medical care in the intervention arm relative to the comparison arm
    - A relevant outcome is defined as an actual/completed outpatient primary HIV medical care visit or HIV viral load and/ or CD4 count when used as proxies for a HIV medical care visit
        - Completed HIV medical visits must be documented in medical records, administrative or agency records, or surveillance reports
        - Self-reports of completed medical visits validated by medical records, administrative or agency records are also acceptable

- For linkage to HIV medical care, a relevant outcome is the actual/completed first HIV medical visit for newly diagnosed HIV-positive persons

- For retention in HIV medical care, a relevant outcome is having actual/completed multiple HIV medical visits over a period of time

- For re-engagement in HIV medical care, a relevant outcome is the actual/completed initial HIV medical visit for HIV-positive persons who have fallen out of, but have returned to, HIV care

- Effect at a required follow-up assessment time point and based on the analyses that meets all study implementation and analysis criteria
- No statistically significant ($p \leq 0.05$) negative intervention effect for any relevant outcome
    - A negative intervention effect is defined as a worsening in linkage to, retention in, or re-engagement in HIV medical care in the intervention arm relative to the comparison arm
- No other statistically significant harmful intervention effect that causes substantial concern
- For an intervention with a replication evaluation, no significant negative intervention effects in the replication study if the intervention was implemented in the exact same way as the original study and with the same or similar cohort/population

Target Population

Black MSM, age 18 and older, at high risk for HIV infection or who are HIV-infected and in need of HIV care and treatment services.

Collaboration/Partnerships

Expected partnerships include: 1) CBOs that are already CMS navigator grantees (NGs) or State Exchange designated organizations (SEDOs) that will add the intervention to their HIV testing and linkage services targeted to black MSM; 2) CBOs that are non-NG/SEDO and that will partner with existing NG/SEDOs to acquire navigators or CACs on an as-needed-basis; and 3) CBOs that are non-NG/SEDO and that will have individual staff members become CACs directly certified by their State Exchange. Key stakeholders include the Centers for Medicare and Medicaid Services (CMS) regional office and Health Resources and Services Administration (HRSA) HIV/AIDS Bureau state program in the applicant's jurisdiction.

Evaluation/Performance Measurement

As part of the application, investigators should include measurable goals and aims based on a three-year research project period. The grantee will collaborate with CDC to: 1) establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the applicant's project plan, and 2) develop and implement project performance measures that are based on specific programmatic objectives.

Examples of goals and aims for this research study will include but not be limited to:

- Developing and implementing research study protocols and consent forms necessary to support the proposed research design for the in-person assistance intervention to help black MSM clients enroll in health insurance or Medicaid.
- Identifying CBO partners and stakeholders, to provide access to medical care, including HIV testing and treatment, substance abuse treatment and prevention services.
- Obtaining appropriate local Institutional Review Board(s) approvals for all participating study sites, as required.
- Obtaining appropriate OMB-PRA approval for data collection instruments and analyses, as required.
- Identifying and enrolling the targeted population of black MSM at high risk for HIV infection or who are HIV-infected and in need of HIV care and treatment services for the intervention and comparison study arms.
- Conducting follow-up assessment and testing for HIV infection or reinfection.
- Developing a guidance document for the implementation of the intervention for black MSM, including recruitment and follow-up of new participants.

Also, funded PIs must submit an annual progress report showing their activities and outcomes based on their overall research goals and timeline. For more information on required Reporting, please see Section VI of this FOA.

Translation Plan

The application should describe how the findings from this study could be used to inform public health policy or practice. During the study period the grantee will develop a guidance document for the implementation of the intervention for black MSM, age 18 and older, including recruitment and follow-up of new participants. This guidance document will be one mechanism for disseminating the project's research findings. Other mechanisms may include conference presentations and publications in peer-reviewed journals.

This section of the application 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 application should identify the research findings that can be used to inform public health policy or practice and how the findings may be adopted in public health settings. The application should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, the application should describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

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

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: $400,000

Year 2: $600,000

Year 3: $500,000

Estimated funding available, including direct and indirect costs, for the first 12-month budget period: $400,000.

Estimated funding available, including direct and indirect costs, for the entire three-year project period: $1,500,000.

Anticipated Number of Awards: 1

The ceiling for an individual award, including direct and indirect costs, for the first 12-month budget period: $400,000.

The floor for an individual award, including direct and indirect costs, for the first 12-month budget period: $0.

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

Award Ceiling: $400,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 3 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations

Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to http:// ecfr.gpoaccess.gov /cgi/t/text/ text-idx?c=ecfr& sid=512ff78311f427c00454772dcf21523a&rgn=div8 &view=text&node=48:1.0.1.6.34.0.1.18& idno=48

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

Additional Information on Eligibility

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

Documentation of the following requirements must be included in the application.

1. Applicant organizations must operate in one of the following eight states: California, Illinois, Maryland, Michigan, New Jersey, New York, Ohio, and Pennsylvania with Medicaid expansion that allows participants with limited incomes to enroll, if needed, and where high HIV prevalence among black MSM was at least 300 HIV diagnoses among black MSM in 2013.
2. The PI from the applying organization must have at least two years of experience delivering HIV-related services targeted to black MSM and this should be evident in the PI’s biosketch, included as part of the application.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

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

Applicants must include each of the following documents in the Letters of Support section of the application:

1. A letter stating that cooperating partners are not already providing these services in-person in conjunction with HIV testing.
2. A letter stating that the applicant organizations or community-based organizational (CBOs) partners are not currently providing in-person health insurance enrollment assistance to clients immediately after, or bundled with, HIV testing.
3. A letter from partner community-based organizations (CBOs), AIDS service organizations (ASOs), or other organizations with an established history of providing services to black MSM, age 18 and older, at high risk for HIV acquisition or transmission, giving the applicant permission to conduct the research and agreeing to collaborate in the implementation of the intervention and the collection, analysis, write up, and presentation of process and outcome data during the entire research period.
4. A letter from the Executive Directors or CEOs of partner/cooperating CBOs, attesting that their organization has been serving black MSM for at least two years prior to the publication date of this Funding Opportunity Announcement, describing their plan to provide CMS navigators or CACs to implement the intervention, and verifying that they are not already providing in-person health insurance enrollment assistance to clients immediately after, or bundled with, HIV testing.
5. A letter from partner HIV treatment facilities stating their willingness to receive linkage referrals from partnering CBOs and to provide the applicant with de-linked data about the referred clients' dates of HIV care visits.

6. Required Registrations

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

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

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.
All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

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

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

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

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

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

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

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

3. Letter of Intent

Due Date for Letter of Intent: **01/07/2016**

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

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

Name of the Applicant

Descriptive title of proposed research

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

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.

2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)

5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table (for New Application ONLY)

9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan.

13. Consortium/Contractual Arrangements

14. Letters of Support

15. Resource Sharing Plan(s)

16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

6. Appendix

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

7. Page Limitations

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

8. Format for Attachments

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

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

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

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

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

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

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

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

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

The application package is not complete until it has passed the Grants.gov/eRA Commons validation

process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

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

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

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

Due Date for Applications: **02/12/2016**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

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.

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

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

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

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

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**
Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.
For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

Does the application include information on the rate of health insurance coverage in the study jurisdiction, overall and among black MSM?

Does the application include information on rates of linkage to, and retention in, HIV-related health care and HIV-associated services in the study jurisdiction, overall and among relevant subpopulations?

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?

Are investigators qualified to carry out this project, and do they have a sufficient percentage of their time committed to this project?

Do the investigators have a thorough understanding of structural and/or policy approaches to HIV prevention?

Do the investigators have experience successfully conducting research with the proposed target population?

Do the applicant investigators and/or investigators at partnering CBOs have at least two years of experience successfully delivering HIV-related services targeted to black MSM?

Do the applicant investigators and/or investigators at partnering CBOs or other collaborating organizations have the ability to collect, manage, and analyze project data in a timely manner?

Do the applicant investigators and/or investigators at partnering CBOs or other collaborating organizations have the appropriate training to implement the required intervention or have plans for obtaining the training?

Innovation

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

Does the application describe how in-person health insurance enrollment assistance is innovative in the proposed settings compared to other known interventions for black MSM?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Does the application document that neither the applicant institution nor a CBO partner are already providing in-person health insurance enrollment assistance to clients immediately after, or bundled with, HIV testing?

Does the application include a logic model that specifies intervention components and their expected outcomes?

Does the application describe how many black MSM the applicant and partners will be able to access during each year of this study?

Does the quality of the proposed research plan, study design, and power analyses adequately address the research objectives of this announcement?

Does the application describe the study jurisdiction’s procedures for linking persons to care (e.g., HIV, PrEP, mental health, substance use) and assisting them to stay in care?

Does the application provide plans for recruitment and follow-up of study participants?

Does the application’s research plan contain pilot-testing data collection instruments; collection and analysis of quality assurance, process, and outcome data; and the measurements listed in Section I.2 Approach (including other health outcome measures)?

Does the application include a plan to collect financial costs from the provider perspective for a cost-benefit analysis?

Does the application contain letters of support from intended partnering CBOs and other organizations and

letters of support from key stakeholders, such as CMS regional offices and HRSA HIV/AIDS Bureau state programs?

Does the application demonstrate that each partnering CBO matches one of the three types listed in Section I.2 Approach?

Is the proposed timeline sufficiently detailed, complete, and realistic for a 3-year project period?

Does the application include copies of standard in-person health insurance enrollment assistance procedures, CMS navigator or CAC training requirements, or other written materials as Appendices?

Does the application propose partnering with more than one type of community-based organization (CBO) to demonstrate the ability to evaluate different ways to implement the intervention?

Does the application include a detailed description of the applicant's and partner organizations' access to, or plan for gaining access to, black MSM at high risk for acquiring or transmitting HIV for purposes of the research project?

Does the application include a detailed description of the applicant's and partner organizations' ability to recruit sufficient numbers of the target population for proposed research activities?

Does the application provide a detailed budget for the total project period that includes a staffing plan and list of activities for each project year?

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?

Will the planned location(s) for the study provide access to adequate numbers of black MSM?

Does the application provide adequate funds to the partner organizations to implement the in-person insurance enrollment assistance intervention?

Does the application provide a description of duties and responsibilities of project personnel, including clear lines of authority and coordination with partnering CBOs and other organizations?

How adequate are the plans for assessment data programming, data processing, analysis capacity, and procedures for data management and security in the application?

Will the data security systems described in the application be sufficient to protect participants' rights and confidentiality?

Additional Review Criteria

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

Biohazards

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

As part of the Biohazards assessment, reviewers will evaluate whether the research proposed qualifies as

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

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. See also: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern at http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

2. Additional Review Criteria

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

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).
If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

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

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of

the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

3. Additional Review Considerations

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

Resource Sharing Plans
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/grants/additionalrequirements/index.html. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.
Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

4. Review and Selection Process

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

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

- Will receive a written critique.

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

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

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf).

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

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

- AR-1: Human Subjects Requirements
- AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3: Animal Subjects Requirements
- AR-7: Executive Order 12372 Review
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR
- AR-21: Small, Minority, And Women-owned Business
- AR-22: Research Integrity
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Release and Sharing of Data

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “;Federal Leadership on Reducing Text Messaging while Driving”;, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 –; FY 2012 Enacted General Provisions

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

The following are additional policy requirements relevant to this FOA:

Dual Use Research of Concern (DURC)

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

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

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

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. For example, CDC may request that the institution periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal. CDC’s Institutional Biosecurity Board (IBB) is responsible for approval of all DURC risk mitigation plans. The award recipient is responsible for adhering to the risk mitigation plan, as approved by CDC. For more information, please see: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern at http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov (http:// www.usaspending. gov/). For the full text of the requirements, please review the following website: https:// www.fsrs.gov/.

Plain Writing Act

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

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

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

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- http://www.cdc.gov/ nccdphp/dnpao/hwi/toolkits/ tobacco/index.htm
- http://www.cdc.gov/nutrition/index.html

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

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations and other HHS, PHS, and CDC grant administration policies.

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

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

- 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.
- Retaining custody of and maintaining primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Developing all materials required for IRB submission (e.g., protocol, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed research study and meet CDC IRB standards.
- Developing quantitative measures of health outcome variables other than HIV status.
- Obtaining all necessary permissions and/or clearances to the study materials.
- Developing and implementing stringent safeguards and procedures for protecting the rights and confidentiality of all study participants.
- Developing recruitment strategies to enroll adequate numbers of the proposed population of eligible black MSM who have not been tested for HIV in the preceding 3 months.
- Identifying, recruiting, obtaining informed consent, enrolling and retaining an adequate number of participants in the research, as determined by the study protocols and the intervention requirements.
- Implementing in-person insurance enrollment assistance with black MSM immediately after (bundled with) HIV testing.
- Ensuring that the study procedures include appropriate referral mechanisms to local resources that provide services to participants (e.g., HIV medical care, mental health counseling, financial services, substance abuse treatment, PrEP, and other services). When feasible, shared measures will be used and recipient organizations' site-specific information, data, and software developed under this award will be combined and made available for analyses by all recipient organizations and CDC, subject to U.S. Government rights of access consistent with current HHS and applicable HHS/CDC policies.
- Collecting all study data, including any laboratory test results that may be proposed.

- Ensuring data entry, security, and quality/accuracy.
- Analyzing data needed to evaluate in-person insurance enrollment assistance with black MSM immediately after HIV testing.
- Submitting all data collected to lead CDC Investigator using encrypted USB.
- Attending periodic meeting(s), as appropriate, at CDC and elsewhere to finalize the research protocol and provide progress updates.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC). http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:
- 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.
- Supplying encrypted USBs for transferring the study data; the USBs will be returned to CDC at the end of the study.
- Providing technical assistance, as needed, in intervention implementation, and the design and conduct of the research.
- Assisting in the development of a research protocol for IRB review and other required reviews and approvals, as needed, by the organizations collaborating in the research project. If CDC is engaged in the research, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
- Conducting ongoing monitoring of grantee implementation and evaluation activities.
- Monitoring and evaluating scientific and operational accomplishments of this project through periodic telephone contacts, site visits, review of technical reports, and interim data analyses. Based on this, CDC will make recommendations aimed at solving problems and improving the quality and timeliness of the research activities.
- Participating in the presentation of results and in preparation of manuscripts/reports for publication, if the CDC contribution so merits.
- 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:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- Preparing an IRB protocol for approval at the local and CDC levels, and other needed reviews and approvals.
- Preparing protocols for other applicable approvals as needed.
- Developing the research study protocols.
- Performing appropriate data analyses as determined by the study collaborators.
- Sharing all data and collaborating with other investigators to answer common research questions.

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/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period**

ends.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm)
  http:// grants.nih.gov/grants/ funding/2590/2590.htm: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
  b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include*:

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

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
    - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
    - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date. Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era). CDC recommends

that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

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

Section VII. Agency Contacts

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

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

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

Program Official / Scientific Research Contact

Deborah Loveys, PhD

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8834

Fax: 404-718-8822

Email: hft6@cdc.gov

Peer Review Contact

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333 Telephone: 404-718-8833

Fax: 404-718-8822

Email: GAnderson@cdc.gov

Financial / Grants Management Contact

Shirley Byrd

Office of Financial Resources

Office of Grant Services
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
2920 Brandy Wine Road, MS E15
Atlanta, GA 30341
Telephone: 770-488-2591
Fax: (770) 488-2828
Email: Yuo6@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.
Sections 301 and 318 of the Public Health Service Act (42 U.S.C. Sections 241 and 247c), as amended.