



**Centers for Disease Control and Prevention**

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

Mobile Messaging Intervention to Present New HIV Prevention Options for MSM

RFA-PS-15-002

Application Due Date: 03/16/2015

Mobile Messaging Intervention to Present New HIV Prevention Options for MSM

RFA-PS-15-002

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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)  
Office of Public Health Scientific Services (OPHSS)

### Funding Opportunity Announcement (FOA) Title

Mobile Messaging Intervention to Present New HIV Prevention Options for MSM

### Activity Code

Applications in response to this FOA will be funded using the U01 activity code.

### Funding Opportunity Announcement Type

New

### Funding Opportunity Announcement Number

RFA-PS-15-002

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

93.941

### Category of Funding Activity:

Health

### FOA Purpose

**Amendment I.** A Summary of the Conference Call held on Tuesday, January 13, 2015 with Potential Applicants for Funding Opportunity Announcement (FOA): PS15-002 “Mobile Messaging Intervention to Present New HIV Prevention Options for MSM” and Answers to Questions from Potential Applicants has been added as an amendment to the FOA in Section VIII. "Other Information" on pages 41-44. Changes made to this FOA to clarify questions from potential applicants has been added in red text on pages 2, 3, 4, 6, 10, 11, 12, 14, 15, 19 and 28.

The purpose of this funding opportunity is to develop and test a mobile messaging (e.g., texting, App) HIV prevention intervention for sexually-active (i.e., had sex with a man in the prior 12 months) gay, bisexual and other men who have sex with men (MSM). The intervention will consist of brief, multi-component messages about new and emerging HIV risk reduction information (e.g., pre-exposure prophylaxis [PrEP] for HIV prevention, post-exposure prophylaxis [PEP], partner benefit of antiretroviral therapy [ART] use, condom effectiveness during use for anal sex, encouragement of periodic HIV testing, importance of ART adherence for optimal benefit). Brief messages will be presented over a 3-month period of time and will target three population groups: 1) HIV-positive MSM, 2) high-risk HIV-negative MSM (i.e., recent anal sex without condoms with a non-primary or HIV-discordant primary partner in the past 3 months), and 3) lower-risk HIV-negative MSM. The prospective grantee will develop a research project that includes Metropolitan Statistical Areas (MSA) from three of the four geographical regions in the United States. One, and only one, location must be in the South (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, and only one location must be in the Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The remaining MSA location will be chosen from the two remaining nationally-designated geographical regions

(Midwest or West). The grantee will partner with appropriate agencies in each MSA location in order to access the target population and to implement study activities. The multi-site project will be conducted in two phases. Phase 1 (n=90) involves conducting formative research to develop intervention content, including custom messages, delivery technology and approach. Phase 2 (n=1206) involves testing the mobile messaging intervention for efficacy in changing HIV prevention behavior in a randomized two (2)-group trial (intervention and delayed intervention arms). **Assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up; an immediate post-intervention assessment will also be given to the delayed intervention arm. For the intervention arm:** the intervention will occur between baseline and the first 3 month assessment and assessments will occur at 3, 6, and 9 months post baseline (also referred to in the table as intervention arm immediate post-test, and 3 and 6-month post-intervention follow-up assessments, respectively). **For the delayed intervention arm:** the intervention will occur between the 9 and 12 month post baseline period (i.e., immediately following the intervention arm 6-month follow-up assessment); assessments for this arm will occur at 3, 6, 9 and 12 months post baseline. **The end point of the RCT 2-arm comparison is at the 6-month post-intervention follow-up assessment for the intervention arm (i.e., 9 months post baseline).** The immediate post-test for the delayed intervention arm (i.e., 12 months post baseline) provides a secondary analysis for within-group change for the delayed intervention arm. Novel, scientifically sound research designs (e.g., partial baseline sample data collection with data imputation) are encouraged.

#### Key Dates

**Publication Date:** To receive notification of any changes to RFA-PS-15-002, return to the synopsis page of this announcement at [www.grants.gov](http://www.grants.gov) and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

**Letter of Intent Due Date:** 02/16/2015

**Application Due Date:** 03/16/2015

90 days after the publication date, by 5:00 PM U.S. Eastern Time. 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., no error correction window).

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:** 05/07/2015

**Secondary Review:** 06/12/2015

**Estimated Start Date:** 09/01/2015

**Expiration Date:** 03/17/2015

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

#### Required Application Instructions

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

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

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

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

## Executive Summary

**Purpose.** The purpose of this funding opportunity is to develop and test a mobile messaging (e.g., texting, App) HIV prevention intervention for sexually-active (i.e., had sex with a man in the prior 12 months) gay, bisexual and other men who have sex with men (MSM). The intervention will consist of brief, multi-component messages about new and emerging risk reduction information (e.g., pre-exposure prophylaxis [PrEP] for HIV infection. Message components that will include, but will not be limited to pre-exposure prophylaxis [PrEP] for HIV infection, post-exposure prophylaxis [PEP], partner benefit of antiretroviral therapy [ART] use, condom effectiveness during use for anal sex, encouragement of HIV testing, importance of ART adherence for optimal benefit). Proposed messaging content, format, frequency, and delivery should reflect the state of the scientific literature at the time of application submission.

Intervention messages will be presented to study participants over a three-month period of time and target three MSM population groups: 1) HIV-positive MSM, 2) high-risk HIV-negative MSM (i.e., self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner), and 3) lower-risk HIV-negative MSM (i.e., no self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner). The prospective grantee will develop a three-region project within Metropolitan Statistical Areas (MSAs)<sup>[1]</sup> with populations of 500,000 or more and located in the four US regions of residence defined by the U.S. Census Bureau<sup>[2]</sup>. So that additional data can be obtained to validate recent trends in HIV incidence in the southern and northeastern US, each research application must identify one, but no more than one, MSA performance site from within the Southern region (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, and but no more than one MSA performance site from the Northeastern region (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The applicant will identify one remaining MSA performance site from the two remaining geographical regions in the US (Midwest or West). The grantee will partner with appropriate agencies within each MSA to improve access to the target population and to implement study activities. The three-region project will be conducted in two phases. Phase 1 (n=90) will involve conducting formative research to develop intervention content, including custom messages and delivery technology whereas Phase 2 (n=1206) will involve testing the mobile messaging intervention for efficacy in changing HIV prevention behavior in a randomized 2-group trial (intervention and delayed intervention arms). **Assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up; an immediate post-intervention assessment will also be given to the delayed intervention arm.**

The prospective grantee will develop mobile technology for message delivery and data collection, as well as preliminary messages using message presentation and delivery approach identified from

Phase 1 and based on the state of public health communication research at the time of application.

Phase 1 (n=90 total, n=30 per site) formative research will include a combination of focus groups (n=45 total, n=15 per site) and participant interviews (n=45 total, n=15 per site). Participant feedback will be used to determine acceptability and appropriateness of message content as well as feasibility of delivery technology and messaging approach for the three-month intervention trial.

The Phase 2 study design will be a randomized 2-group trial (intervention and delayed intervention arms) with both study arms receiving the brief mobile messaging HIV prevention intervention plus provision of standard-of-care services. The intervention group will receive three-month intervention messaging immediately following baseline assessment, and the delayed intervention group will receive the three-month intervention immediately following final assessment at 6 months. Again, assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up; an immediate post-intervention assessment will also be given to the delayed intervention arm.

Standard-of-care services for HIV-negative MSM, regardless of risk level, includes provision of an HIV test (based on the local HIV testing standard procedure) as described below. Standard-of-care services for HIV-positive MSM include provision of linkage to HIV care services based on the standard-of-care services offered in the local project site community.

A sample size of approximately 1206 MSM (603 per study arm) will include 402 men recruited in each of three MSAs with one, but no more than one, MSA site located in the South (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, but no more than one MSA site located in the Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The remaining MSA location will be chosen from the two remaining nationally-designated geographical regions (Midwest or West). Within each MSA site, equal proportions (134/134/134) of the study participants will be HIV-positive, HIV-negative high-risk and HIV-negative lower-risk MSM. Baseline HIV status will be measured by self-report (including self-perceived status for men who have not been tested). Given that HIV testing will be included in intervention message content and is also an outcome of interest, providing testing for HIV-negative/unknown status participants at study baseline would be expected to bias data on self-initiated HIV testing behavior. Therefore, all HIV-negative/unknown status men will be provided access to HIV testing resources at the six-month post-intervention follow up assessment or study endpoint. Importantly, participants are expected to continue normal healthcare activities during the course of the study and to be offered HIV testing referral information and perhaps even on-site testing through existing service providers.

Primary study outcomes of interest will include participant behavior data after exposure to HIV risk reduction and prevention messaging (e.g., HIV testing, condom use, PrEP, PEP or ART use) as assessed at baseline, and at three- and six-months post-intervention follow-up. Multiple HIV prevention messages will be presented daily via mobile technology (e.g., texting, App) over a 3-month time period. The messages will be tailored for each of the three targeted MSM populations and self-reported baseline prevention behaviors (e.g., self-reported PrEP use among high-risk MSM, ART use and viral suppression among HIV-positive MSM). HIV testing will be offered to all HIV-negative and HIV-unknown status participants at the six-month follow-up.

[1] MSA areas with populations of 500,000 or more according to the OMB Bulletin 10-02. <http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf>. Published December 1, 2009. and as indicated in CDC's 2011 HIV Surveillance Report Table 23 and 24 [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf)

[2] Four US regions as defined by the US Census: [https://www.census.gov/geo/maps-data/maps/pdfs/reference/us\\_regdiv.pdf](https://www.census.gov/geo/maps-data/maps/pdfs/reference/us_regdiv.pdf)

**Mechanism of Support.** Cooperative agreement.

**Funds Available and Anticipated Number of Awards.** Estimated total funding available, to include direct and indirect costs for the entire project period, is \$3,800,000. The project period will be four years. There will be one award. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. The total amount awarded will depend on 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) will be \$600,000. The estimated total funding (direct and indirect) for the second year (12-month budget period) will be \$600,000, the third year (12-month budget period) will be \$1,300,000, and the fourth year (12-month budget period) will be \$1,300,000. The project period will run from 09/01/2015 to 08/31/2019.

**Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. "Application and Submission Information" of this announcement.

**Eligible Institutions/Organizations.** Institutions/organizations listed in Section III. 1. are eligible to apply.

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

**Number of PDs/PIs.** There will only be one PD/PI for this project. Co-investigators can be identified from local partnering agencies/project sites.

**Number of Applications.** The eligible applicant institution may submit only one application.

**Application Type.** New

**Special Date(s).** A potential applicant conference call will be held on Tuesday, January 13, 2015 from 1:00 pm to 2:00 pm Eastern Time. The bridgeline number is 1-866-662-8986; passcode 8378091.

**Application Materials.** See Section IV.1 for application materials.

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

## Part 2. Full Text

### Section I. Funding Opportunity Description

#### Statutory Authority

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

## 1. Background and Purpose

CDC announces a cooperative agreement funding opportunity announcement titled “Mobile Messaging Intervention to Present New HIV Prevention Options for MSM” to develop and systematically evaluate a brief mobile messaging HIV prevention intervention for reducing HIV-related risk behaviors among HIV-positive and HIV-negative gay, bisexual and other men who have sex with men (MSM).

Sexual risk behavior among MSM in the U.S. increased from 2005-2011 among subgroups of men who have sex with men (MSM), a group already disproportionately affected by HIV (1). At the same time, messaging on the range and complexity of HIV risk reduction options is becoming increasingly challenging. As new information about prevention options continues to emerge from the scientific community, this information must be translated clearly and concisely to populations at highest risk for HIV infection, such as MSM. New and complex scientific information about pre-exposure prophylaxis (PrEP) for HIV prevention, post-exposure prophylaxis (PEP), condom efficacy during anal sex, ART adherence benefit for non-infected partners, and lack of HIV testing among some MSM, and other prevention-relevant information, needs to be combined to present multi-component messaging in effective ways to 1) HIV-positive MSM, 2) high-risk HIV-negative MSM (i.e., self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner) and 3) lower-risk HIV-negative MSM (i.e., no self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner). **Importantly, these three target groups are distinct from each other with respect to the prevention messages that will be most appropriate for them.** For example, ART medication adherence is important for HIV-positive MSM, and PrEP/PEP are viable HIV prevention methods for high-risk HIV-negative MSM but not lower-risk MSM. Research has demonstrated that mobile messaging is a promising approach to brief intervention messaging for HIV risk reduction strategies and medication adherence in MSM target groups.

The purpose of this FOA is to develop and test a brief mobile messaging (e.g., texting, App) HIV prevention intervention for sexually-active (i.e., had sex with a man in the prior 12 months) gay, bisexual and other men who have sex with men and will consist of multi-component messages about new and emerging HIV risk-reduction information delivered over a three-month period of time. Proposed messaging content, format, frequency, and delivery technologies used in this study are expected to reflect the state of the scientific literature at the time of application submission. The FOA study will consist of formative research and experimental Randomized Control Trial (RCT) phases conducted in three geographically diverse US MSAs with one, but no more than one MSA located in the Southern region (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, but no more than one MSA located in the Northeastern region (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The remaining MSA location will be chosen from the two remaining nationally-designated geographical regions (Midwest or West). The 2-arm RCT will include randomization of participants to intervention or delayed intervention arms. **Assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up; an immediate post-intervention assessment will also be given to the delayed intervention arm.**

## References

1) Centers for Disease Control and Prevention. HIV Testing and Risk Behaviors Among Gay, Bisexual, and Other Men Who Have Sex with Men — United States. *MMWR* 2013a; 62(47);

958-962. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6247a4.htm>. Accessed 9/29/2014.

2) CDC. Diagnoses of HIV infection in the United States and dependent areas, 2011. HIV surveillance report. Vol. 23. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at: [http://www.cdc.gov/hiv/library/reports/surveillance/2011/surveillance\\_report\\_vol\\_23.html](http://www.cdc.gov/hiv/library/reports/surveillance/2011/surveillance_report_vol_23.html) or [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf) Accessed 9/29/2014.

3) Centers for Disease Control and Prevention. *HIV Surveillance Report, 2011*; vol. 23. <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>. Published February 2013. Accessed 9/29/2014.

**Research Objectives:** Applications submitted under this FOA **must** address all of the following research objectives (Additional details are provided in Part 2, Section I.2: Approach). Applicants will:

1. Identify three MSAs from separate and distinct geographical regions within the US with one of these MSAs located in the US Southern region (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, but no more than one MSA located in the Northeastern region (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The remaining MSA location will be chosen from the two remaining nationally-designated geographical regions (Midwest or West).
2. Partner with HIV prevention service organizations (including, but not limited to, local health departments, community-based organizations, community health centers, and other agencies) that serve gay, bisexual and other MSM target populations whose sociodemographics (e.g., race/ethnicity and socioeconomic status) are representative of each of the three proposed regional MSA sites with populations of 500,000 or more.
3. Develop a mobile, brief messaging (e.g., texting, App) HIV behavioral intervention about new and emerging HIV prevention methods through relevant formative research (Phase 1) in HIV-positive and HIV-negative (high-risk, lower-risk) MSM.
4. Evaluate the efficacy of a mobile, brief messaging HIV behavioral intervention delivered over a three-month period to reduce risk behaviors (e.g., number of anal sex partners) and increase protective behaviors for HIV-negative (e.g., condom use, PrEP/PEP use, HIV testing) and HIV-positive (e.g., condom use, ART use and adherence, viral load testing) MSM (Phase 2).

**Scientific knowledge to be achieved:**

1. The extent to which a brief mobile messaging (e.g., texting, App) HIV behavioral intervention can successfully change behaviors and attitudes of MSM.
2. The important components and feasibility of implementing a brief mobile messaging (e.g., texting, App) HIV behavioral intervention among HIV-positive, high-risk HIV-negative (i.e., self-reported recent anal sex without condoms with a non-primary partner or a serodiscordant primary partner) and lower-risk HIV-negative MSM (i.e., no self-reported recent anal sex without condoms with a non-primary partner or a serodiscordant primary partner).

**Health Equity.** The program supports efforts to improve the health of populations disproportionately affected by HIV/AIDS, viral hepatitis, 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 <http://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 their 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/2020/topics-objectives/topic/hiv>]. 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**

The NCHHSTP of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" and measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA addresses the "Healthy People 2020" priority area of HIV and is in alignment with: 1) performance goal HIV-1 (developmental) to reduce new HIV diagnoses among adolescents and adults; 2) performance goal HIV-2 to reduce new (incident) HIV infections among adolescents and adults; performance goal HIV-10 to increase the proportion of HIV-infected adolescents and adults who receive HIV care and treatment consistent with current standards by 2020; performance goal HIV-14.2 (developmental) to increase the proportion of MSM who have been tested for HIV in the past 12 months; and HIV-18 (developmental) to reduce the proportion of MSM who reported unprotected anal sex in the past 12 months. For more information, please see <http://www.healthypeople.gov/2020/topics-objectives/topic/hiv>

The National HIV/AIDS Strategy (NHAS) has also set goals and this proposed study supports goal 1 to prevent new HIV infections, goal 2 to increase access to care and improve health outcomes for people living with HIV, and goal 3 to reduce HIV-related health disparities. For more information, please see <http://aids.gov/federal-resources/national-hiv-aids-strategy/overview/index.html>

Also related to NHAS, this study is in support of the White House's HIV Care Continuum Initiative which calls for coordinated action to increase the number of people living with HIV in the United States who have achieved the treatment goal of controlling the HIV virus. For more information, please see <http://aids.gov/federal-resources/policies/care-continuum/>

**CDC's Winnable Battles:** This FOA addresses one of CDC's Winnable Battle goals by:

- Intensifying HIV prevention efforts in communities where HIV is most heavily concentrated.
- Expanding 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.
- Maximizing the proportion of people with HIV who have suppressed viral load by improving

- diagnosis, linkage and retention in care, and antiretroviral provision and adherence.
- Improving data monitoring, dissemination, and feedback.
- Educating Americans about the threat of HIV and how to prevent it.

## Public Health Impact

Gay, bisexual and other MSM continue to be at disproportionate risk for HIV infection compared to others in the United States at a time when new scientific information is emerging about new HIV prevention options. This project will develop and test the efficacy of a brief mobile messaging HIV prevention intervention delivered over a three-month period to HIV-positive MSM, and high- and lower-risk HIV-negative MSM. The ultimate goal is to develop a cost efficient and scalable intervention that incorporates the most current information about options for reducing risk for HIV transmission among MSM.

## Relevant Work

Centers for Disease Control and Prevention. HIV Testing and Risk Behaviors Among Gay, Bisexual, and Other Men Who Have Sex with Men — United States. *MMWR* 2013a; 62(47);958-962.

CDC's 2011 HIV Surveillance Report: Centers for Disease Control and Prevention. *HIV Surveillance Report, 2011*; vol. 23. Published February 2013b. Accessed July, 29, 2014. <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>.

PRS Efficacy Criteria for Best-Evidence (Tier I) Risk Reduction (RR) Individual-level, Group-level, and Couple-level Interventions (ILIs/GLIs/CPLs). Last Updated April, 2014. Accessed October 4, 2014. [http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence\\_ILIs\\_GLIs.html](http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence_ILIs_GLIs.html)

The Health Communicator's Social Media Toolkit. Last Updated July 2011. Accessed October 10, 2014. [http://www.cdc.gov/healthcommunication/toolstemplates/socialmediatoolkit\\_bm.pdf](http://www.cdc.gov/healthcommunication/toolstemplates/socialmediatoolkit_bm.pdf)

## 2. Approach

CDC is proposing the *Mobile Messaging Intervention to Present New HIV Prevention Options for MSM* FOA for the development and testing of an HIV prevention intervention for sexually-active (i.e., had sex with a man in the prior 12 months) HIV-positive, high-risk (i.e., recent anal sex without condoms with a non-primary or HIV-discordant primary partner in the past three months) HIV-negative and lower-risk HIV-negative gay, bisexual and other men who have sex with men. After award, CDC will collaborate with one grantee to develop a trial protocol. Although some details of the randomized 2-group trial will be determined after award, the intended core activities and study outcomes are presented in this FOA.

The grantee will oversee formative research (Phase 1) to develop the brief mobile messaging HIV prevention intervention for targeted groups of HIV-positive and HIV-negative MSM. Messages may be tailored to baseline prevention method utilization of individual participants (e.g., self-reported use of PrEP, PEP, ART and condoms). The grantee will oversee implementation of the randomized controlled trial in three MSA project sites with populations of 500,000 or more from three of the four US geographic regions as identified by the US Census and in Table 23 of CDC's 2011 HIV Surveillance Report. See: [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf). One, but no more than one, location will be in the US South (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia) and one, but no more than

one location will be in the Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont). The remaining MSA location will be chosen from the two remaining nationally-designated geographical regions (Midwest or West) due to high HIV incidence or diagnoses in these regions (see Relevant work, CDC 2013b).

Applicants will select and establish partnerships with relevant agencies (e.g., health departments, community-based organizations, HIV/STD care clinics, community health centers) in each of the three proposed MSA project sites (one must be located in the US South and one site must be located in the US Northeast) to establish a credible presence in the community and facilitate successful completion of the proposed project activities. Partner agencies must serve gay, bisexual and other MSM to satisfy the minimum sample size specified in this FOA. Applicants should include in their application **letters of support for the research from partners** and a description of how and why the collaborating agencies were selected.

Letters of support should include:

- A statement of the collaborating agency's role in the project;
- Estimates of the total number of HIV-positive and HIV-negative MSM that have received HIV prevention services annually during the past three years and the applicant's ability to recruit and retain large samples of MSM in randomized trial studies, including 1) HIV-positive MSM, 2) high-risk HIV negative MSM (recent anal sex without a condom) and 3) lower-risk HIV negative MSM (no recent anal sex without a condom) as required by this study;
- Statement of their resources and commitment to the success of the study, including any skills or experiences that may make them uniquely qualified to serve as a study partner;
- Intent to enter into formal agreements for participation (e.g., **Memoranda of Understanding, Contracts**) for the entire four (4) years of the project period.

During Phase 1 of the study, each MSA project site will recruit and enroll a minimum of 30 MSM (n=90 combined) – including 30 HIV-positive, 30 high-risk HIV-negative MSM, and 30 lower-risk HIV-negative MSM – for the formative research (see Table 1). During Phase 2, each project site will recruit and enroll 402 MSM (n=1206 combined) for the behavioral intervention randomized trial (see Table 2), with approximately one-third in each of the three messaging target groups. A common assessment tool must be developed and employed across the three project sites. Given the importance of a sexual partner's role in prevention option decisions (e.g., ART and PrEP/PEP use, viral load monitoring) and the different social contexts of sexual decision-making for primary and non-primary partners, each site will assess behavior with both primary and non-primary partners.

**Formative Research (Phase 1).** The purpose of Phase 1 is to assist in developing multi-component brief messages that will be presented to MSM study participants via mobile messaging technology over a three-month intervention period and further test efficacy in Phase 2 of the study. Phase 1 of the study (three-to-six months) will consist of both focus groups and individual interviews to develop a brief assessment tool to measure collective risk reduction and overall individual perceived protective value (i.e., potential combined benefit of using multiple prevention options over time, such as condoms, HIV testing, ART, PrEP, PEP, etc.) and pilot-test intervention message content, presentation (approach), and mobile messaging technology (e.g., texting, App). The minimum sample size per MSA project site will be 30 MSM (total sample of 90 across all three sites; see Table 1), with half assessed through focus groups and half through individual interviews.

**Table 1. Target sample size by subgroup for formative research (Phase 1)**

|        | HIV-positive | <u>HIV-negative</u> |            | Combined |
|--------|--------------|---------------------|------------|----------|
|        |              | High-risk*          | Lower-risk |          |
| Site 1 | 10           | 10                  | 10         | 30       |
| Site 2 | 10           | 10                  | 10         | 30       |
| Site 3 | 10           | 10                  | 10         | 30       |
|        | 30           | 30                  | 30         | 90       |

\*Anal sex without condoms with a non-primary or HIV-discordant primary partner in the past three months.

**Behavioral Intervention Trial (Phase 2).** Phase 2 will encompass a 24-month phase of the study which involves implementation of a randomized trial to test the efficacy of the multi-component HIV prevention messaging intervention developed in Phase 1. Novel scientifically sound research designs (e.g., partial baseline sample data collection with data imputation) are strongly encouraged but must include the following components and study design elements: eligibility screening, informed consent, study arm randomization, and exposure to three-month intervention messaging. Study assessments will measure behavior change and multiple prevention method usage over time in a randomized 2-group trial. Assessments for the intervention arm will occur at baseline (immediately following study enrollment), and at three and six months post-baseline intervention. **Assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up (see Table 3); an immediate post-intervention assessment will also be given to the delayed intervention arm.** Rapid HIV testing will be directly provided to all interested HIV-negative participants at the study endpoint, and referrals to HIV testing and care services will be provided to all participants at any time point during the study.

The brief assessment tool developed during Phase 1 will measure collective risk reduction and overall individual perceived protective value (i.e., potential combined benefit of using multiple prevention options over time, such as condoms, HIV testing, ART, PrEP, PEP, etc.) during Phase 2.

Post-intervention outcomes (see “Objective and Outcomes” in Section I.2 below for more detail) will consist of self-reported sexual risk behaviors risk reduction method usage, and overall individual HIV risk reduction across prevention options for primary and non-primary partners by target group (HIV-positive, and high- and lower-risk HIV-negative MSM).

**Table 2. Target sample size by subgroup for the behavioral intervention trial (Phase 2)**

|        | <u>HIV-negative</u> |          |            |       |            |       |          |       | Total |
|--------|---------------------|----------|------------|-------|------------|-------|----------|-------|-------|
|        | HIV-positive        |          | High-risk* |       | Lower-risk |       | Combined |       |       |
|        | Interv(a)           | Delay(b) | Interv     | Delay | Interv     | Delay | Interv   | Delay |       |
| Site 1 | 67                  | 67       | 67         | 67    | 67         | 67    | 201      | 201   | 402   |
| Site 2 | 67                  | 67       | 67         | 67    | 67         | 67    | 201      | 201   | 402   |
| Site 3 | 67                  | 67       | 67         | 67    | 67         | 67    | 201      | 201   | 402   |
|        | 201                 | 201      | 201        | 201   | 201        | 201   | 603      | 603   | 1206  |

\* Anal sex without condoms with a non-primary or HIV-discordant primary partner in the past three months.

a Intervention group

b Delayed intervention group

**Table 3. Behavioral intervention trial study design**

|                                 | Baseline | Intervention Occurs | Intervention Post-test | 3-month Follow Up | 6-month Follow Up | Intervention Occurs | Delayed Intervention Post-test |
|---------------------------------|----------|---------------------|------------------------|-------------------|-------------------|---------------------|--------------------------------|
| <b>Timeline</b>                 | 0 months |                     | 3 months               | 6 months          | 9 months          |                     | 12 months                      |
| <b>Intervention Arm</b>         | A        | XXXXXXXX            | A                      | A                 | A                 |                     |                                |
| <b>Delayed Intervention Arm</b> | A        |                     | A                      | A                 | A                 | XXXXXXXX            | A                              |
|                                 |          |                     |                        |                   |                   |                     |                                |

A = assessment

X = intervention

**Proposal Design and Analysis.** The applicant must submit a *plan for the design* of the proposed evaluation of intervention outcomes that meets published standards or criteria for providing “best evidence” of intervention efficacy in reducing HIV risk behaviors. These standards from the scientific literature have been summarized and are discussed in greater detail online at [http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence\\_ILIs\\_GLIs.html](http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence_ILIs_GLIs.html).

To satisfy the design criteria for providing “best evidence” of intervention efficacy, the design for the proposed evaluation must include the following elements

- Prospective design; that is, collection of assessment data at baseline (prior to delivering the intervention) and at one or more points after the intervention has been delivered (see details below);
- A concurrent comparison / delayed intervention group;
- Random assignment to intervention and delayed intervention groups;
- **Informed consent, study arm randomization, and exposure to three-month intervention messaging groups - assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up (see Table 3) - an immediate post-intervention assessment will also be given to the delayed intervention arm;**
- A strategy to retain at least 80 percent of participants in the intervention and delayed intervention groups for data collection at all planned follow-up assessments;
- The measurement of relevant outcomes (see “Objective and Outcomes” section below for more details) such as behaviors that directly impact risk of HIV infection.

The applicant must submit a *plan for analysis* of evaluation results that includes the following elements:

- A comparison of the intervention group and the delayed intervention group on relevant outcomes;
- A comparison of groups as originally assigned; that is, regardless of the amount of intervention exposure (i.e., intention-to-treat analysis);
- Use of appropriate cluster-level analyses, if participants are assigned to intervention and comparison conditions by cluster or group (e.g., study site);

- Analyses based on pre-/post-intervention changes in measures (if pre-/post-intervention changes are used in analyses, outcome measures must be identical, including the recall period);
- Alpha = 0.05 and 2-sided statistical test.

In addition, the design for the proposed evaluation during Phase 2 must include:

- A sample that includes a minimum of 603 participants in the intervention group and a minimum of 603 participants in the concurrent comparison delayed intervention group.

## **Objectives/Outcomes**

The objective and desired outcome of this FOA is to develop a mobile technology messaging intervention (including prevention messages and delivery system) for MSM that is tested for behavior change efficacy in a randomized 2-group trial. Prevention messages are to be tailored for and tested among three target groups: HIV-positive, and high- and lower-risk HIV negative MSM. Outcomes include change in use of HIV prevention methods (from baseline to follow-up) that are the subject matter of multiple messages delivered over a three-month period.

Primary outcomes are behaviors based on the content of the prevention messages, which are to be determined by the HIV serostatus/risk-level group including, but not limited to, the following:

- HIV-negative MSM (both high-risk and lower-risk):
  - Overall number of (a) insertive and (b) receptive non-primary anal sex partners with whom a condom was not used (past three months);
  - Percentage of anal sex acts with condom use with non-primary partners (past three months);
  - Percentage of anal sex acts with condom use with HIV discordant primary partners (past three months);
  - HIV testing behavior (past three months);
  - STD testing behavior (past three months).
- High-risk HIV-negative MSM (i.e., recent anal sex without condoms with a non-primary or HIV-discordant primary partner in the past three months):
  - PrEP/PEP uptake and adherence (past three months).
- HIV-positive MSM:
  - Overall number of non-primary anal sex partners (past three months);
  - Overall number of (a) insertive and (b) receptive non-primary anal sex partners with whom a condom was not used (past three months);
  - Percentage of anal sex acts with condom use with non-primary partners (past three months);
  - Percentage of anal sex acts with condom use with discordant primary partners (past three months);
  - ART uptake and adherence (past three months);
  - Viral load testing behavior and results (past three months);
  - STD testing behavior (past three months).

Secondary outcomes are behavioral intentions to use, knowledge of and beliefs about the content of the prevention messages by HIV serostatus group. For example:

- HIV-negative MSM (both high-risk and lower-risk):

- Intent to reduce number of anal sex partners (next three months);
  - Intent to reduce overall number of (a) insertive and (b) receptive non-primary anal sex partners with whom a condom was not used (past three months);
  - Intent to use condoms during anal sex with non-primary partners (next three months);
  - Intent to use condoms during anal sex with discordant primary partners (next three months);
  - Intent to get an HIV test (next three months);
  - Intent to get tested for STDs (next three months).
- High-risk HIV-negative MSM (i.e., recent anal sex without condoms with a non-primary or HIV-discordant primary partner in the past three months):
    - Intent to uptake and adhere to PrEP/PEP regimens (next three months).
  - HIV-positive MSM:
    - Intent to reduce number of anal sex partners (next three months);
    - Intent to reduce overall number of (a) insertive and (b) receptive non-primary anal sex partners with whom a condom was not used (past three months);
    - Intent to use condoms during anal sex with non-primary partners (next three months);
    - Intent to use condoms during anal sex with discordant primary partners (next three months);
    - Intent to uptake and adherence to ART regimens (next three months);
    - Intent to get a viral load test, and/or reduce or maintain low viral load (next three months);
    - Intent to get tested for STDs (next three months).

## Target Population

Sexually-active (i.e., had sex with a man in the prior 12 months) gay, bisexual and other men who have sex with men (MSM).

## Collaboration/Partnerships

Applicants will establish support (Letters of Support to be provided with application) and formal agreements (e.g., **Memoranda of Understanding, Contracts**) from partnering agencies in three US MSAs (project sites) selected from three distinct US geographical regions, of which one MSA will be identified within the US South and one identified within the US Northeast. Applicants are encouraged to collaborate with large HIV prevention service provider agencies in the three selected MSAs. These collaborating agencies should serve a patient population whose sociodemographics (e.g., race/ethnicity and socioeconomic status) are representative of MSM in those jurisdictions.

## Evaluation/Performance Measurement

**a. Formative Research (Phase 1).** A combination of focus groups and individual interviews will be conducted with each of the three target MSM population groups: 1) HIV-positive, and 2) high-risk HIV-negative MSM (unprotected anal sex with a non-primary partner in the past three months) and 3) lower-risk (all other MSM) HIV-negative MSM. Formative research content for HIV-negative MSM will include qualitative message testing regarding condom use, PrEP/PEP use, number of sex partners, HIV testing, and other message content areas as determined relevant. For HIV-positive MSM, qualitative message testing will include condom use, ART use, number of sex partners, viral

load testing, and other relevant message content. Other formative research content areas include mobile technology use and preferences. Focus group and interview recordings will be transcribed and coded for analysis using appropriate qualitative research software. Results should suggest direction for developing and refining messages, as well as appropriate technology and procedures for message delivery in the Phase 2 intervention trial.

**b. Behavioral Intervention Trial (Phase 2).** As a randomized 2-group trial of a HIV prevention behavioral intervention, research is the central focus of the FOA. In addition to intervention efficacy, the grantee is expected to measure usability, understandability, and believability of the HIV prevention messages delivered. Mobile device internal tracking of intervention program usage is also expected, including measurement of additional prevention, care and referral information seeking to links or supplemental information included through the mobile messaging intervention program. A study coordinator should be assigned to each of the three regional MSA project sites.

Applicants should develop a timeline to achieve study milestones and develop metrics to monitor the trial’s performance and progress. The designated study coordinators will track the number of participants recruited by each collaborating agency and the aggregate number of participants who have been randomized. **Assessments will occur simultaneously for both arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up (see Table 3); an immediate post-intervention assessment will also be given to the delayed intervention arm.** The primary outcomes will evaluate differences in change of behaviors based on the content of the prevention messages, which are determined by the HIV serostatus group as described earlier. To have adequate statistical power to detect change, an estimated 1206 MSM should be enrolled and then randomized to the active intervention or delayed intervention arms, with n=201intervention and n=201delayed intervention participants in each of the three HIV-status/risk groups (HIV-positive, and high- and lower-risk HIV-negative men).

**Translation Plan**

The project will develop and evaluate the efficacy of a brief mobile messaging (e.g., texting, App) HIV prevention intervention to reduce HIV risk behaviors among HIV-positive and HIV-negative gay, bisexual and other MSM. The ultimate goal is to demonstrate an efficacious intervention for delivering HIV prevention messages to at-risk MSM that could potentially be adopted by HIV service provider agencies throughout the United States as a behavioral intervention to improve HIV care and reduce HIV acquisition and transmission. The application should describe a plan for translating this intervention to HIV service provider agencies.

**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:** \$3,800,000

**Anticipated Number of Awards: 1**

Year 1: \$600,000 total

Year 2: \$600,000 total

Year 3: \$1,300,000 total

Year 4: \$1,300,000 total

Number of awards = 1

Estimated total funding available for first year (12-month budget period) \$600,000 including direct and indirect costs.

Estimated total funding available for entire project period is \$3,800,000 for 4 years, including direct and indirect costs.

The award ceiling and floor described below are for the first 12-month budget period only.

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

**Award Ceiling:** \$600,000 Per Budget Period

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

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

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

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

### Section III. Eligibility Information

#### 1. Eligible Applicants

Eligibility Category:

- State governments
- County governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public housing authorities/Indian housing authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
- Private institutions of higher education
- For profit organizations other than small businesses
- Small businesses

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](http://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**

Not applicable.

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

Not applicable.

#### 5. Responsiveness

The following documentation **must** accompany all applications to document successful capacity to achieve the study objectives and to be responsive to this FOA:

a) The applicant must partner with HIV prevention service organizations including, but not limited to, local health departments, community-based organizations, community health centers, and other agencies from MSAs with populations of 500,000 or more from within three of the four distinct US geographical regions<sup>[1]</sup>. One, but no more than one, of these geographical regions must be located in the US South (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, or West Virginia). Partner agencies will be relevant agencies in MSAs with populations of 500,000 or more within the proposed regional areas according to OMB Bulletin 10-02 and Table 23 of CDC's 2011 HIV Surveillance Report; see: <http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf> and [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf). Partner agencies must serve gay, bisexual and other MSM and serve a patient population whose sociodemographics (e.g., race/ethnicity and socioeconomic status) are representative of MSM in the project city's jurisdiction.

b) The applicant must partner with HIV prevention service organizations including, but not limited to, local health departments, community-based organizations, community health centers, and other agencies from MSAs with populations of 500,000 or more from within three of the four distinct US geographical regions<sup>[1]</sup>. One, but no more than one, of these geographical regions must be located in the US Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont). Partner agencies will be relevant agencies in MSAs with populations of 500,000 or more within the proposed regional areas according to OMB Bulletin 10-02 and Table 23 of CDC's 2011 HIV Surveillance Report; see: <http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf> and [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf). Partner agencies must serve gay, bisexual and other MSM and serve a patient population whose sociodemographics (e.g., race/ethnicity and socioeconomic status) are representative of MSM in the project city's jurisdiction.

c) The applicant must designate the following minimum key project staff positions in their application:

- Principal Investigator (PI) of this application, who must be able to contribute, at minimum, 20% of his/her time to this project;
- Project manager able to contribute a minimum of 50% time;
- On-site project coordinators able to contribute a minimum of 50% time;
- Programmer/data manager able to contribute 25 to 50% time.

d) The applicant must include in their application, Letters of Support from each proposed MSA partner agency. Letters of Support should include:

- A statement of the collaborating agency's role in the project;
- Estimates of the total number of HIV-positive and HIV-negative MSM that receive HIV prevention services annually during the past three years and the agency's ability to recruit and

retain large numbers of MSM in RCT studies, including HIV-positive, and high- (recent anal sex without a condom) and lower-risk (other) HIV negative MSM as required by this study;

- Statement of their resources and commitment to the success of the study, including any skills or experiences that may make them uniquely qualified as a partner.
- The intent to enter into a formal agreement for participation (e.g., **Memoranda of Understanding, Contract**) for the entire four (4) years of the project period.

e) The applicant must submit a **plan for the design** of the proposed evaluation of intervention outcomes and a **plan for analysis** of evaluation results that includes the following elements that meet published standards or criteria for providing “best evidence” of intervention efficacy in reducing HIV risk behaviors as described at [http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence\\_ILIs\\_GLIs.html](http://www.cdc.gov/hiv/dhap/prb/prs/efficacy/rr/criteria/bestEvidence_ILIs_GLIs.html).

[1] Four US regions as defined by the US Census: [https://www.census.gov/geo/maps-data/maps/pdfs/reference/us\\_regdiv.pdf](https://www.census.gov/geo/maps-data/maps/pdfs/reference/us_regdiv.pdf)

## 6. Required Registrations

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

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

All applicant organizations must register with **Grants.gov**. Please visit [www.Grants.gov](https://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 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](http://www.Grants.gov).

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

### **2. Content and Form of Application Submission**

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

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

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit

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

These forms can be downloaded and uploaded at the following link: <http://grants.nih.gov/grants/forms.htm>

### 3. Letter of Intent

Due Date for Letter of Intent: **02/16/2015**

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

By the date listed in Part 1. Overview Information, prospective applicants are provided the option of submitting 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

If submitted, a letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

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

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### 4. Required and Optional Components

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

### 5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application

Guide ([http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)) for additional

information. Please attach applicable sections of the following Research Plan components as directed in Part

## 2, Section 1 (Funding Opportunity Announcement Description).

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

- 1. Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
- 2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
- 3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
- 4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
- 5. Progress Report Publication List** (for Continuation ONLY)

### Human Subjects Section

- 6. Protection of Human Subjects**
- 7. Inclusion of Women and Minorities**
- 8. Targeted/Planned Enrollment Table** (for New Application ONLY)
- 9. Inclusion of Children**

### Other Research Plan Sections

- 10. Vertebrate Animals**
- 11. Select Agent Research**
- 12. Multiple PD/PI Leadership Plan.**
- 13. Consortium/Contractual Arrangements**
- 14. Letters of Support**
- 15. Resource Sharing Plan(s)**
- 16. Appendix**

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

All instructions in the SF424 (R&R) Application Guide

([http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)) must be followed along with any additional instructions provided in the FOA.

### **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](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)).**

## 9. Submission Dates & Times

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

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

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

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

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

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

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

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

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; [support@grants.gov](mailto:support@grants.gov)). If the

system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; [www.pgotim@cdc.gov](mailto:www.pgotim@cdc.gov) for guidance at least 3 calendar days before the deadline date.

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

#### **Unsuccessful Submissions:**

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

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

Due Date for Applications: **03/16/2015**

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

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

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

#### **11. Funding Restrictions**

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

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

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.

Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, forms, plans. etc.) from 10 or more non-Federal individuals/entities are subject to PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.

#### **12. Other Submission Requirements and Information**

Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a grant/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.

Under the Paperwork Reduction Act, a Federal agency sponsoring a standardized data collection or directly obtaining standardized or substantially similar information from ten or more persons in any 12-month period must obtain advance written approval from the OMB.

This document contains collection of information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard 424(R&R) and PHS 398 Forms have been approved by the Office of Management and Budget (OMB) under the control numbers 0925-0001, 0925-0002, and 4040-0001). It is also requested that a Standard Form (SF) 425 be completed. This form's approved OMB Control number is 0348-0061 and expires 2/28/2015.

Note: Notwithstanding any other provision of law, no person is required to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

### **Application Submission**

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

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

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

### **Important reminders:**

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

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

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

See more resources to avoid common errors and submitting, tracking, and viewing applications: [http://grants.nih.gov/grants/ElectronicReceipt/avoiding\\_errors.htm](http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm) or [http://grants.nih.gov/grants/ElectronicReceipt/submit\\_app.htm](http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm)

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

## Section V. Application Review Information

### 1. Criteria

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

### Overall Impact

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

### Scored Review Criteria

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

#### Significance

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

Does the application adequately discuss the changing HIV prevention information field for MSM?

Does the application explain why brief messaging of new HIV prevention information is important, particularly through a mobile messaging format?

Does the application adequately describe relevant experience with brief messaging interventions and mobile technology?

#### Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Do the investigators have relevant experience developing brief HIV prevention messaging interventions?

Do the investigators have relevant experience developing interventions using mobile technology?

Do the investigators have the appropriate training and skills to conduct the study?

Do the investigators have experience managing or collaborating large, multi-site RCT trials of behavioral interventions with MSM?

## **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?

Do the investigators currently use or test mobile messaging in their projects?

Do the investigators currently address new and emerging HIV prevention information in their projects?

Do the investigators present a novel yet well-founded application using mobile technology to present brief messages about new and emerging HIV prevention information with 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 study design include eligibility screening, informed consent, randomization to intervention and delayed intervention study arms, and three-month message exposure components?

Do the investigators describe the details of their proposed intervention to present messages on new HIV prevention information to MSM over a 3-month period through mobile messaging technology?

Are adequate plans presented in the application for monitoring message delivery and receipt, for potential interactive as well as one-way mobile communications, for customizing and tracking messaging for each participant, and for adequately measuring outcomes at follow up?

Does the application clearly describe study outcomes?

Does the application describe an appropriate sampling approach to successfully enroll MSM participants in this multi-regional MSA project?

Is the randomization approach adequately described in the application and appropriate for the study?

Are sound retention efforts appropriately presented in the application?

Does the application address content of the messaging and technology approach, including local resource information (e.g., HIV testing locations, ART and PrEP/PEP medications) built into the program for participants?

Does the application address the issue of collecting process level data on message comprehension and technology utilization, including immediate acknowledgement of message receipt and pursuit

of additional prevention information or resources?

Does the formative research portion of the application adequately address:

- Recruitment and enrollment of MSM into focus groups and individual interviews?
- Qualitative data collection, transcription, coding, and analysis?
- Development and refinement of prevention messages and mobile delivery technology?

Does the RCT portion of the application address these critical elements of “best evidence” randomized research trials:

- Random or minimally biased assignment of subjects to study arms?
- At least an 80% retention rate at a single follow-up assessment for each study arm?
- Comparison between intervention arm and delayed intervention arm?
- Analysis based on post-intervention levels or on pre-post changes in measures?
- Analysis based on an  $\alpha = 0.05$  (or more stringent) and a 2-sided test?

Does the study design include:

- Simultaneous assessments for both intervention arms at three-month intervals starting with a common baseline through six-month post-intervention follow-up?
- An immediate post-intervention assessment for the delayed intervention arm?

## Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Does the investigator propose partnerships with HIV prevention service organizations including, but not limited to, local health departments, community-based organizations, community health centers, and other agencies in MSAs with populations of 500,000 or more from within three of the four US geographical regions (one MSA must be located in the US South and one MSA must be located in the US Northeast) as identified in OMB Bulletin 10-02 and Table 23 of CDC’s 2011 HIV Surveillance Report; see: <http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf> and [http://www.cdc.gov/hiv/pdf/statistics\\_2011\\_HIV\\_Surveillance\\_Report\\_vol\\_23.pdf](http://www.cdc.gov/hiv/pdf/statistics_2011_HIV_Surveillance_Report_vol_23.pdf)?

Does the application describe documented basic capacity/support in data management and analysis to conduct this study and designate experienced key staff for Principal Investigator (PI) (minimum, 20% effort), Project Manager (minimum of 50% effort), On-site Project Coordinators (minimum, 50% effort) and Programmer/Data Manager (25-50% effort) roles?

Does the application describe how the collaborating sites were selected and present adequate need for including the proposed sites?

Does the application include Letters of Support from collaborating agencies and are Letters of Support included in the application from each of the proposed MSA project area partner agencies?

Does the application include collaborating sites representative of HIV prevention and service agencies that serve MSM in the selected cities?

Does the application describe how data will be securely collected and managed within and across the study sites?

Does the application describe how confidentiality is assured for participants at the study sites?

## 2. Additional Review Criteria

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

### Protections for Human Subjects

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

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

([http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm#ar1](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1)).

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

### Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research

([http://www.cdc.gov/maso/Policy/Policy\\_women.pdf](http://www.cdc.gov/maso/Policy/Policy_women.pdf) and

<http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://www.cdc.gov/maso/Policy/policy496.pdf>).

### Vertebrate Animals

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

([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150)).

### Biohazards

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

### 3. Additional Review Considerations

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

#### Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: [http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm#ar25](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25). Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

#### Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

### 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.
- Funding recommendations may also consider geographic diversity (e.g., applications that increase the diversity of geographic regions defined by the US Census ([https://www.census.gov/geo/maps-data/maps/pdfs/reference/us\\_regdiv.pdf](https://www.census.gov/geo/maps-data/maps/pdfs/reference/us_regdiv.pdf)))

### 5. Anticipated Announcement and Award Dates

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

## Section VI. Award Administration Information

## 1. Award Notices

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

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

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

## 2. CDC Administrative Requirements

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

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

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

Specific requirements that apply to this FOA are the following:

Generally applicable ARs: [http://www.cdc.gov/od/pgo/funding/grants/additional\\_req.shtm](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm)

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2010](#)

[AR-12: Lobbying Restrictions](#)

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

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

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

[AR-22: Research Integrity](#)

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

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

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

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

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

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

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

ARs applicable to HIV/AIDS Awards:

[AR-4: HIV/AIDS Confidentiality Provisions](#)

[AR-5: HIV Program Review Panel Requirements](#)

[AR-6: Patient Care](#)

Organization Specific ARs:

[AR-8: Public Health System Reporting Requirements](#)

[AR-15: Proof of Non-profit Status](#)

[AR 23: Compliance with 45 C.F.R. Part 87](#)

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

To view brief descriptions of relevant CDC requirements visit: [http:// www.cdc.gov/ od/pgo/funding/ grants /additional req.shtm](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm)

CDC Assurances and Certifications:

All applicants are required to sign and submit “Assurances and Certifications” documents indicated at <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>.

Applicants may follow either of the following processes:

- \* Complete the applicable assurances and certifications on an annual basis, name the file “Assurances and Certifications” and upload it as a PDF file at [www.grants.gov](http://www.grants.gov) or
- \* Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at:

[http://wwwn.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/Homepage.aspx)

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

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

The following are additional policy requirements relevant to this FOA:

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

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

[http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol memo.html](http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html)

## **Federal Funding Accountability and Transparency Act of 2006**

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

## **Tobacco and Nutrition Policies**

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

### **Tobacco:**

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

### **Nutrition:**

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

- [http://www.gsa.gov/graphics/pbs/Guidelines for Federal Concessions and Vending Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)

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

- <http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>

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

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

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

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

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

- Collaborating with community partners and CDC to develop a single, unified protocol and submitting the protocol for IRB approvals as required locally. Protocol development activities will include recruitment and retention activities, methods to measure the study outcomes, and data management procedures.
- Obtaining appropriate approvals from local Institutional Review Board(s) (IRBs) from all participating study sites, if required.
- Mobile technology program development for message delivery and information access.
- Recruiting and enrolling adequate numbers of HIV positive, and high- and lower-risk HIV negative MSM participants, including randomization to study arms.
- Retaining participants through the entire period of participation of the study.
- Establishing procedures to maintain the rights and confidentiality of all participants in this trial.
- Performing data analyses as determined in the study protocols.
- Collaborating with CDC to disseminate study results at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Participating in routine conference calls with the CDC project officer and research team.
- Hosting CDC project officer site visits.
- Developing data management systems to collect information necessary for the project.
- Transferring data to CDC at least monthly.
- Awardees will retain custody of the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Reporting surveillance and program results as required by local law.
- PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: "This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention". In addition, the PI/PD must provide to CDC Program the abstracts or

manuscripts prior to any publication related to this funding. The grantee will not seek to publish results or findings from this project without prior approval and clearance from CDC.

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

- Providing technical assistance as needed in the design and conduct of the research.
- Facilitating and assisting in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. A CDC engagement determination will determine if the CDC IRB will also need to approve the protocol.
- Paperwork Reduction Act (PRA) eligibility will depend upon the evaluation and reporting methods to be used for each activity and if applicable, project managers are advised to submit a PRA determination form for each of the activities and or contact the NCHHSTP OMB Coordinator as soon as the data collection instruments and methods for evaluation have been developed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting, as needed, in designing a data management system.
- Facilitating storing of aggregate data with participating recipients.
- Collaborating with grantees to disseminate study results at national or international meetings and publishing research findings in peer-reviewed scientific literature.
- Conducting site visits to ensure that collaborating clinics have been properly selected, collaborations outlined in proposals are appropriate, the community is involved in the research activities, and investigators are complying with the research protocol.
- Conducting initial and subsequent meetings of the study investigators to facilitate the exchange of research progress among recipients and to offer additional technical expertise for the conduct of research.

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.
- Organizing agenda content for conference calls and planning meetings as needed.
- Attending investigator meetings and participating in conference calls for the purposes of assessing overall progress, problem solving, and for program evaluation purposes.
- Collaborating on presentation and publication of data as warranted.

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

- Named in the NOA as the Program Official to provide overall scientific and programmatic stewardship of the award;
- Serves as the primary point of contact on official award-related activities including an annual review of the grantee's performance as part of the request for continuation application;
- Makes recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application;
- Carries out continuous review of all activities to ensure objectives are being met;
- Attends committee meetings and participates in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and

- Monitors performance against approved project objectives.

## 5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrc.gov](http://www.fsrc.gov) on all subawards over \$25,000. See the HHS Grants Policy Statement ([http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

CDC is also requiring the submission of Non-Competing Continuation Progress Report Forms (PHS 2590). The use of these forms are covered by OMB Control numbers 0925-0001 and 0925-0002 (Expiration Date 08/31/2015).

### 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, [http:// www. cdc.gov/ od/pgo/ funding/ forms.htm](http://www.cdc.gov/od/pgo/funding/forms.htm) and at [http:// grants.nih.gov/grants/ funding/2590/ 2590.htm](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://grants1.nih.gov/grants/funding/2590/2590.htm))  
[http:// grants.nih.gov/grants/ funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm): Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
  - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
  - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*
  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*
  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:
  - Detailed operational plan for continuing activities in the upcoming budget period, including

updated Measures of Effectiveness for evaluating progress during the upcoming budget period.  
Report listed by Research Aim/Project.

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

## 2. Annual Federal Financial Reporting

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

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

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

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

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

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

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

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

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

## Section VII. Agency Contacts

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

### Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Procurement and Grants Office

Telephone 770-488-2700

Email: [PGOTIM@cdc.gov](mailto:PGOTIM@cdc.gov)

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

**Program Official / Scientific Research Contact(s)**

Deborah Loveys, PhD

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8834

Fax: 404-718-8640

Email: [hft6@cdc.gov](mailto:hft6@cdc.gov)

**Peer Review Contact(s)**

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director for Science

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

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

1600 Clifton Road, MS E-60

Atlanta, GA 30333

Telephone: 404-718-8833

Fax: 404-718-8822

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

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

Jon Messick

Procurement and Grants Office

Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
2920 Brandywine Road, MS E15  
Atlanta, GA 30341  
Telephone: (770) 488-2897  
Fax: (770) 488-2868  
Email: [yfa4@cdc.gov](mailto:yfa4@cdc.gov)

## Section VIII. Other Information

Other CDC funding opportunity announcements can be found at [www.grants.gov](http://www.grants.gov).

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

### Authority and Regulations

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

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

## Summary of the Conference Call held on Tuesday, January 13, 2015 with Potential Applicants for Funding Opportunity Announcement (FOA): PS15-002 “Mobile Messaging Intervention to Present New HIV Prevention Options for MSM” and Answers to Questions from Potential Applicants.

### A. Introductory Comments

Any scientific or technical questions should be addressed to Deborah Loveys ([hft6@cdc.gov](mailto:hft6@cdc.gov)). Any questions on financial, grants management, or eligibility aspects should be addressed to Jon Messick ([yfa4@cdc.gov](mailto:yfa4@cdc.gov)). Questions regarding the Peer Review process should be addressed to Greg Anderson ([gca5@cdc.gov](mailto:gca5@cdc.gov)). Their contact information can be found in the FOA, Part 2, Section VII. “Agency Contacts”. Information on application submission is listed in Section IV. “Application and Submission Information”.

### B. Eligibility Information

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

### C. Required Registrations

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

### D. Other Information

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

Potential applicants should pay close attention to Part 2, Section V. “Application Review Information, 1. Criteria”. The criteria must be addressed – these are the criteria that will be used by reviewers to score the application. Failure to provide required information could result in an unfavorable score. Please also pay close attention to Part 2, Section I. “Funding Opportunity Description, 2. Approach”. Applicants must respond to ALL objectives listed. All responses to Objectives should be written in “SMART” format, which

means that they should be specific, measurable, appropriate, realistic, and time-based.”

Please remember that the Research Plan Narrative is limited to 25 pages. Also remember to submit a 4-year Research Plan and a budget for each year.

It is anticipated that there will be 1 award. The estimated total funding available for Year 1 is \$600,000. The estimated total funding for the entire project period is \$3,800,000. The floor amount is \$500,000 for the first year, including direct and indirect costs. The ceiling amount is \$600,000 for the first year, including direct and indirect costs. Awards issued under this FOA are contingent upon the availability of funds.

#### **E. Questions and Answers:**

**1. Question:** Are the SMART objectives required to be included in the narrative?

**Answer:** All objectives must be addressed in the research narrative and should be in SMART format.

**2. Question:** Are recruitment or interviews required to be face-to-face?

**Answer:** Face-to-face interviews are not necessarily required. Face-to-face or outreach field recruitment is not required; however, a balanced recruitment approach is expected so that not all participants are recruited by a single approach, such as online recruitment.

**3. Question:** Section III.5 of the FOA deals with the project’s minimum key staff. Are these required for each year? Also, regarding key project staff efforts, do the current requirements in the FOA apply to the trial phase (Years 3 and 4) or to the entire project period?

**Answer:** The staffing levels noted in this section refer to minimum levels expected over the 4-year study period, whenever relevant staff are active on the project. This includes, but is not limited to, the trial phase of the study.

**4. Question:** In regard to the behavioral intervention trial design: It is stated that the delayed intervention will begin after 6 months and then there will be the 3 month intervention, and 3 month and 6 month follow-up. With the delayed intervention, there is only time for a 9 month follow-up and no parallel design? How do we address this?

**Answer:** We have included clarifying language and added a supporting table of the intervention trial design in the attached amended FOA (Table 3). Assessments will occur for both arms at three-month intervals, starting with a common baseline. **For the intervention arm**, the intervention will occur between baseline and the first 3-month assessment and assessments will occur at 3, 6, and 9 months post baseline (also referred to in the table as intervention arm immediate post-test, and 3 and 6-month post-intervention follow-up assessments, respectively). **For the delayed intervention arm**, the intervention will occur between the 9 and 12 month post-baseline period (i.e., immediately following the intervention arm 6-month follow-up assessment); assessments for this arm will occur at 3, 6, 9 and 12 months post-baseline. **The end point of the RCT 2-arm comparison is at the 6-month post-intervention follow-up assessment for the intervention arm (i.e., 9 months post-baseline).** The immediate post-test for the delayed intervention arm (i.e., 12 months post baseline) provides a secondary analysis for within-group change for the delayed intervention arm.

**5. Question:** In regard to the MSM target populations identified in the FOA: Does this require that the intervention will target every type of MSM or is it OK to target a subpopulation?

**Answer:** The FOA identifies that “Intervention messages will be presented to study participants over a three-month period of time and target three MSM population groups: 1) HIV-positive MSM, 2) high-risk

HIV-negative MSM (i.e., self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner), and 3) lower-risk HIV-negative MSM (i.e., no self-reported recent anal sex without condoms with a non-primary partner or an HIV serodiscordant primary partner)” and “with approximately one-third in each of the three messaging target groups.” Additionally, the FOA requests three distinct US regional sites. Given these requirements for sampling, additional requirements (e.g., age range, race/ethnicity) were not made.

**6. Question:** The FOA states that the intervention design will come out of the formative stage. However, do you want some indication of what is being proposed?

**Answer:** Yes, we would like some idea of what you are proposing. The Behavioral Intervention Trial (Phase 2) “involves implementation of a randomized trial to test the efficacy of the multi-component HIV prevention messaging intervention developed in Phase 1. Novel, scientifically sound research designs (e.g., partial baseline sample data collection with data imputation) are strongly encouraged but must include the following components and study design elements: eligibility screening, informed consent, study arm randomization, and exposure to three-month intervention messaging.”

The research plan section of the application should contain sufficient detail to clearly identify the activities and specific study components included in the Behavioral Intervention Trial study design proposed.

**7. Question:** Page 24 talks about OMB submission requirements. Will CDC help in obtaining these?

**Answer:** Yes. CDC program staff will work with the awardee to address any OMB PRA requirements.

**8. Question:** Do we need to provide power calculations for our sample sizes given that the FOA provides suggestions of sample size?

**Answer:** Yes.

**9. Question:** The budget starts out slowly for the first two years and then takes off. Is this because the trial is expected in years 3 and 4?

**Answer:** Yes, the Behavioral Intervention Trial (Phase 2) is expected to be performed during years 3 and 4.

**10. Question:** Can you clarify what the approval process will be for the messaging developed for the intervention?

**Answer:** CDC will work cooperatively with the awardee throughout the study period. There will be clearances at CDC for study messaging and communications, as part of the study approval process.

**11. Question:** On page 9 of the FOA and throughout the document, it states “Applicants will select and establish partnerships (letters of support for the research proposal and Memoranda of Understanding) with relevant agencies (e.g., health departments, community-based organizations, HIV/STD care clinics, community health centers) in each of the three proposed MSA project sites.” If we are applying as an academic/research institution from one MSA, do the other project sites from MSA #2 and MSA #3 have to be a health department, CBO, clinic, health center, or some other HIV prevention service organization?

Or can the three project sites from the three MSAs be academic/research institutions? And then each project site will select and partner with HDs, CBOs, health centers within their respective MSA area to help with recruitment and implementation, etc.?

If this is the case, then does each project site need to provide letters of support/MOUs from relevant agencies within their respective MSA area?

**Answer:** As identified in Part 1. Overview Information, FOA Purpose, “The prospective grantee will develop a research project that includes Metropolitan Statistical Areas (MSA) from three of the four geographical regions in the United States.” and “The grantee will partner with appropriate agencies in each MSA location in order to assess the target population and to implement study activities.” The awardee can establish partnerships with any relevant agency that meets the requirements for service to the target population. The FOA identifies several types of relevant partner agencies but does not require the awardee to partner with specific types of organizations in any of the chosen geographical regions or MSAs.

As indicated in Part 2. Section I.2. Approach, “Applicants should include in their application a description of how and why the collaborating agencies were selected.”

Part 2. Section III.5. Responsiveness indicates that “The applicant must include in their application, Letters of Support from each proposed MSA partner agency.”

**12. Question:** In regard to sample size, how was it determined in the FOA? There's a list of primary outcomes (e.g., number of partners, HIV testing). When we present power calculations, which outcomes should we primarily base our power on?

**Answer:** The applicant should present an understanding of the intended sample size based on statistical power calculations for primary behavioral outcomes in their proposal. Demonstration of power calculations should be centered on primary behaviors addressed in the applicant’s proposed mobile messaging intervention. Examples of potential primary outcome behaviors would be recent condom use, PrEP initiation/adherence, ART initiation/adherence, HIV testing, etc.

**13. Question:** The appendix guidelines say that you can include 10 PDF documents. I am having a little trouble interpreting the guidance. The guidance states: 10 PDF documents - so does that mean that each page is a separate document or would one manuscript be a separate document? I typically upload all of the proposed instruments in the appendix so would each instrument be considered one PDF document?

**Answer:** Do not use the appendix to circumvent the page limits of any section of the application for which a page limit exists. A maximum of 10 PDF attachments is allowed in the Appendix. The intent of the guidance is to equate “attachment” with a discrete file type or item and that each attachment will have a distinct, descriptive file name.

For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>.

**14. Question:** We will have a formal sub-contract with each of our study sites at the time of the application. Is a Memorandum of Understanding still required?

**Answer:** The FOA states that: “Applicants will establish support (Letters of Support to be provided with application) and formal agreements (Memorandum of Understanding) from partnering agencies in three US MSAs...” and that letters of support from partners should include a statement regarding the intent to enter into an agreement.

We have made an amendment to the FOA to clarify that a Memorandum of Understanding is one example of an agreement that is acceptable.