Centers for Disease Control and Prevention

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

Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons who have Sex with Men

RFA-PS-16-003

Application Due Date: 02/12/2016
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### Part 1. Overview Information

**Participating Organization(s)**

Centers for Disease Control and Prevention

**Components of Participating Organizations**

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

**Funding Opportunity Announcement (FOA) Title**

Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons who have Sex with Men

**Activity Code**

U01 Research Project Cooperative Agreements

**Funding Opportunity Announcement Type**

New

**Funding Opportunity Announcement Number**

RFA-PS-16-003

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

93.941

**Category of Funding Activity:**

Health

**FOA Purpose**

The purpose of this funding opportunity announcement (FOA) is to support a project to evaluate locally-developed or adapted and potentially effective interventions that are designed to deliver a combination of HIV prevention, HIV care and treatment, and other support services to transgender persons who have sex with men, who are at high risk of HIV infection or who are living with HIV. Combination HIV prevention interventions are defined for the purpose of this FOA as a combination of mutually reinforcing biomedical, behavioral, and social/structural intervention components that together either reduce participants’ risks for acquiring HIV or improve outcomes along the HIV care continuum.

**Key Dates**

**Publication Date:** To receive notification of any changes to RFA-PS-16-003, 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:** 01/12/2016

**Application Due Date:** 02/12/2016
On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 04/26/2016
Secondary Review: 05/25/2016
Estimated Start Date: 09/30/2016
Expiration Date: 02/13/2016

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

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose.** The purpose of this FOA is to support a project to evaluate locally-developed or adapted and potentially effective but insufficiently evaluated, interventions that are designed to deliver a combination of HIV prevention, HIV care and treatment, and other social and support services to transgender persons who have sex with men, who are at high risk of HIV infection or who are living with HIV. Combination HIV prevention interventions are defined for the purpose of this FOA as a combination of mutually reinforcing biomedical, behavioral, and social/structural intervention components that together either reduce participants’ risks for acquiring HIV or improve outcomes along the HIV care continuum. The applicant may select one or more of the following Options:

  - **Option A:** Combination HIV prevention interventions that target HIV *infected* transgender persons who have sex with men who are at risk for HIV infection. Required intervention components should include at least one of the following: 1) Linking newly diagnosed persons to HIV care; 2) retaining persons currently in HIV care; 3) re-engaging persons who have fallen out of regular HIV care or who were never successfully linked to HIV care.

  - **Option B:** Combination HIV prevention interventions that target HIV *uninfected* transgender persons who have sex with men. Required intervention components should include at least one of the following: 1) HIV testing; 2) behavioral HIV risk reduction; and 3) pre-exposure prophylaxis (PrEP)/post-exposure prophylaxis (PEP).

For each Option above, combination HIV prevention interventions should include at least one intervention component that addresses a social/structural determinant of health (for example, delivery of housing assistance, job training, mental health services, etc.) that enables transgender persons who have sex with men to access and utilize HIV prevention and care services.

Combination HIV prevention interventions must have been locally developed or locally adapted by the
applicant or partnering Community Based Organization (CBO), Community Health Center (CHC) or Community Service Organization (CSO), and may be referred to as ‘homegrown’ combination HIV prevention interventions. They may be delivered directly as co-located services or as co-located and referral services.

- **Mechanism of Support.** Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards.** The estimated total funds available for this FOA is $3,600,000. The anticipated number of awards is two (2). Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $400,000 for two awards (approximately $200,000 per awardee). The estimated total funding (direct and indirect) for the entire 4-year project period is $3,600,000 for two awards (approximately $1,800,000 per awardee). The project period will run from 09/30/2016 to 09/29/2020.

The estimated funding per awardee by 12-month budget period is:

- **Year 1:** $200,000
- **Year 2:** $600,000
- **Year 3:** $600,000
- **Year 4:** $400,000

- **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 per application. If necessary, Co-PI(s) may be listed in the application but only one PI may be the primary CDC contact for the award and this must be indicated in the application.
- **Number of Applications.** Eligible applicant institutions may submit only one application.
- **Application Type.** New.
- **Special Date(s).** Not applicable.
- **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**
1. Background and Purpose

There are approximately 700,000 transgender persons living in the US (1). The National HIV/AIDS Strategy has identified transgender persons as a priority population for targeting HIV prevention activities and reducing health disparities (2). A 2008 review of studies found that, on average, 28% of transgender women tested positive for HIV, and rates were highest among African American transgender women (56%) (3); other studies of transgender women have reported similar or higher estimates of HIV infection (4,5). In addition, the percentages of transgender women testing positive for HIV infection are comparable to or higher than percentages among men who have sex with men based on multi-city surveys conducted in 2008 and 2011 (6). Many transgender women report high rates of sex and drug use behaviors, engage in sex work activities, may inject hormones and silicone using unclean injection equipment and substances, and prioritize gender reassignment over HIV risks (3, 7-10). Transgender persons, including transgender youth, experience social isolation, stigma, gender-related violence and discrimination (transphobia), which can impact access to employment, housing, and education and can lead to mental health and substance use issues (3,4). Given the range of social determinants that can affect HIV infection and participation in HIV-related care by transgender women, effective HIV prevention strategies for these populations will need to provide a combination of social services to address both behavioral factors and social and structural determinants of health. The Centers for Disease Control and Prevention’s (CDC’s) Compendium of Evidence-based Interventions and Best Practices for HIV Prevention has not identified any HIV prevention interventions or best practices for transgender participants that satisfy CDC’s evidence-based criteria for efficacy (11). Several risk reduction interventions have been developed for transgender women (12-18); however, four have not been rigorously evaluated and two are currently undergoing randomized controlled trials (RCTs - primary data collection to be completed in 2015 and 2017) (16,17).

The purpose of the project to be funded by this FOA is to evaluate locally-developed or adapted and potentially effective but insufficiently evaluated, interventions that are designed to deliver a combination of HIV prevention, HIV care and treatment, and other support services to transgender persons who have sex with men. Combination HIV prevention interventions are defined for the purpose of this FOA as a combination of mutually reinforcing biomedical, behavioral, and social/structural intervention components that together either reduce participants’ risks for acquiring HIV or improve outcomes along the HIV care continuum. The applicant may select one or more of the following Options:

- **Option A**: Combination HIV prevention interventions that target HIV *infected* transgender persons who have sex with men who are at risk for HIV infection. Required intervention components should include at least one of the following: 1) Linking newly diagnosed persons to HIV care; 2) retaining persons currently in HIV care; and 3) re-engaging persons who have fallen out of regular HIV care or who were never successfully linked to HIV care.

- **Option B**: Combination HIV prevention interventions that target HIV *uninfected* transgender persons who have sex with men. Required intervention components should include at least one of the following: 1) HIV testing; 2) behavioral HIV risk reduction; and 3) PrEP/PEP.

For each Option above, combination HIV prevention interventions should include at least one intervention component that addresses a social/structural determinant of health (for example, delivery of housing assistance, job training, mental health services, etc.) that enables transgender persons who have sex with men to utilize HIV prevention and care services.

Interventions that do not currently address social and structural determinants of health but have evaluation data that support the integration of social/structural components into existing HIV prevention or treatment services will also be considered.

Social/structural intervention components that are considered able to reduce the barriers to HIV care for transgender persons who have sex with men may include, but are not limited to:
1. Access to general health care services, such as:
   a. Medical or dental care;
   b. STD testing and treatment;
   c. Substance abuse treatment;
   d. Hepatitis testing and treatment;
   e. Mental health services;
   f. Gender reassignment/transitioning safety (hormone/silicone/surgical).
2. Job training and placement.
3. Legal aid.
4. Housing assistance.
5. Transportation assistance (vouchers, tickets, vehicle access).
6. Strategies for countering transphobia, stigma, and/or racism.
7. Intervention components that address other social and structural determinants of health that have been shown to negatively impact HIV prevention and care for transgender persons.

Combination HIV prevention interventions must have been locally developed or locally adapted by the applicant or partnering Community Based Organization (CBO), Community Health Center (CHC) or Community Service Organization (CSO), and may be referred to as ‘homegrown’ combination HIV prevention intervention.

Combination interventions may be delivered directly as co-located services or as co-located and referral services to transgender persons who have sex with men who are at high risk for HIV infection or who are living with HIV.

The application should provide evidence that the proposed homegrown combination HIV prevention intervention meets the following requirements:

- Intervention activities have been developed or adapted with substantial input from the served community of transgender persons.
- Intervention components for HIV negative persons address at least one of the following: 1) HIV testing; 2) behavioral interventions; and 3) PrEp/nPEP.
- Intervention components for HIV positive persons address at least one of the following: 1) Linking newly diagnosed persons to HIV care; 2) retaining persons currently in HIV care; and 3) re-engaging persons who have fallen out of regular HIV care or who were never successfully linked to HIV care.
- Intervention components address at least one social/structural determinant of health for transgender persons enabling them to access and utilize HIV prevention and care interventions OR evidence (from user feedback, process evaluation data) that the integration of at least one social/structural intervention component will improve access to and utilization of existing HIV prevention and care interventions for transgender persons who have sex with men.
- The intervention has been delivered to transgender persons who have sex with men during routine service delivery for a minimum of three (3) consecutive years prior to the publication date of this funding opportunity announcement.
- Data have been collected suggesting that the intervention is potentially effective for reducing HIV-related risk behaviors or improving HIV care and treatment outcomes for transgender persons who have sex with men.
- The intervention has not been previously rigorously evaluated and
- Has written curricula and/or implementation guides or manuals; standard operating procedures or policies; and internal written documentation of intervention activities used to deliver each component of the homegrown combination intervention.

Homegrown interventions that are not acceptable for this FOA:

1. Combination interventions for transgender persons who have sex with men that have already undergone a rigorous outcome evaluation.
2. Interventions delivered to students as part of a school-based curriculum.
3. Interventions which propose social/structural components for which there is no evidence of need from the target population.
4. Interventions that have not been delivered to the target population for at least three (3) consecutive years.
5. Interventions for which there are no formalized documentation materials or procedures (e.g., curricula and/or facilitator guides or manuals, standard operating procedures or policies, or internal written documentation of intervention activities).

The project will support an evaluation of up to two locally developed or locally adapted combination interventions as described above.

References:


**Health Equity:**

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

Health disparity is a particular type of health difference that is closely linked with social or economic disadvantage based on racial or ethnic group, religion, socioeconomic status, gender, mental health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or other characteristics historically linked to discrimination or exclusion [HP 2020 - [http://www.healthypeople.gov/2010/np2020/advisory/Phase1/glossary.htm](http://www.healthypeople.gov/2010/np2020/advisory/Phase1/glossary.htm)]. Health disparities in HIV, viral hepatitis, STDs, and TB are inextricably linked to a complex blend of social determinants that influence which populations are most severely affected by these diseases.

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

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

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and

- Continuous efforts to maintain a desired state of equity after particular health disparities are eliminated.

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

Healthy People 2020 and other National Strategic Priorities
This FOA aligns with the National HIV Prevention Strategy’s three primary goals of:

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

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

- HIV-2: Reduce the number of new HIV infections among adolescents and adults.
- HIV-3: Reduce the rate of HIV transmission among adolescents and adults.
- HIV-9: Reduce the proportion of persons with a diagnosis of Stage 3 HIV (AIDS) within 3 months
  of diagnosis of HIV infection.
- HIV-13: Increase the proportion of persons living with HIV who know their serostatus.
- HIV-14: Increase the proportion of adolescents and adults who have been tested for HIV in the past
  12 months.
- HIV-17: Increase the proportion of sexually active persons who use condoms
- HIV-12: Reduce deaths from HIV infection.
- HIV-19: Increase the proportion of persons who are linked to HIV medical care within 3 months of
  HIV diagnosis.
- HIV-20: Increase the proportion of persons with an HIV diagnosis who had at least one HIV medical
  care visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days
  between medical visits.
- HIV-21: Increase the proportion of persons with an HIV diagnosis in medical care who were
  prescribed antiretroviral therapy for the treatment of HIV infection at any time in the 12-month
  measurement period.
- HIV-22: Increase the proportion of persons with an HIV diagnosis in medical care with a viral load
  <200 copies/mL at the last test during the 12-month measurement period.
- HIV-23: Reduce the proportion of persons with an HIV diagnosis receiving HIV services that were
  homeless or unstably housed in the 12-month measurement period.

This FOA aligns very closely with the three key strategies of CDC’s HIV winnable battle effort:

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

Additional strategic priorities:
2. CDC Division of HIV/AIDS Prevention (DHAP) Strategic Plan: http://www.cdc.gov/hiv/pdf/policies_D
   HAP-strategic-plan.pdf
   -hiv-care-continuum-initiative
Public Health Impact
Although CDC’s prevention efforts have averted more than 350,000 HIV infections in the U.S. and saved more than $125 billion in medical costs from 1991-2006, transgender persons, especially transgender persons who have sex with men, continue to be at disproportionate risk for HIV infection compared to others in the United States. In addition, transgender persons are disproportionately impacted by multiple social determinants of health which influence HIV prevention, care and treatment among transgender persons, including housing instability, experiences of social discrimination and violence, and institutional stigma. The National HIV/AIDS Strategy has identified transgender persons as a priority population for targeting HIV prevention activities and reducing health disparities. The proposed activities will evaluate interventions developed by affected communities for the purpose of identifying best practices for national dissemination. This FOA has the potential to identify best practice combination HIV prevention interventions for transgender persons who have sex with men and contribute to reducing HIV infection among this vulnerable population.

Relevant Work


2. Approach

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

This FOA will support projects to partner with agencies (CBOs, CHCs, and CSOs) to implement and evaluate locally developed or locally adapted homegrown combination HIV prevention intervention for transgender persons who have sex with men. It is intended that the findings from this evaluation will be used to improve the quality of HIV prevention services for transgender persons who have sex with men.

The application can select one or more of the following Options for their proposed evaluation:

- **Option A**: Combination HIV prevention interventions that target HIV infected transgender persons who have sex with men. If the combination approach targets transgender persons who are living with
HIV, the application should specify the components of the combined intervention that reduce behavioral HIV transmission risks and increase linkage to, retention and re-engagement in HIV care and treatment. These positive outcomes should include but need not be limited to reductions in risk behaviors (e.g., condomless sex) that can result in HIV transmission to sex partners, follow-up to care after initial linkage to care for newly diagnosed persons, retention in HIV care during regular visits to HIV care providers, re-engagement in care following lapses in care, and viral suppression. The application should also describe how the components or activities in the combination HIV prevention intervention address (or propose with evidence) at least one social and structural determinant of health that can negatively affect access to and participation by HIV-positive transgender persons who have sex with men in HIV prevention and related care. These components of the combination intervention may include but need not be limited to the delivery of medical, dental, or mental health services, substance abuse treatment, STD and hepatitis testing and treatment, job training and placement, legal aid, housing, transportation assistance, strategies for countering trans/homophobia and/or racism, and gender reassignment/transitioning safety (hormone/silicone/surgical). These service components may be delivered directly as co-located services or as co-located and referral services to transgender persons who are infected with HIV.

**Option B:** Combination HIV prevention interventions that target HIV uninfected transgender persons who have sex with men who are at risk for HIV infection. If the combination approach targets HIV-negative transgender persons, the application should specify the components of the combined intervention that reduce behavioral HIV risks among transgender participants. These risk-reduction outcomes should include but need not be limited to increased HIV/STD testing, reductions in HIV-related risk behaviors (e.g., sex or drug injection behaviors), increased use of PrEP/nPEP. The application should also describe how the components or activities in its combination approach address (or propose with evidence) at least one social/structural factor that can negatively affect access to and participation by HIV uninfected transgender persons who have sex with men in HIV prevention. These components of the combination intervention may include but need not be limited to the delivery of medical, dental, or mental health services, substance abuse treatment, STD and hepatitis testing and treatment, job training and placement, legal aid, housing, transportation assistance, strategies for countering trans/homophobia and/or racism, and gender reassignment/transitioning safety (hormone/silicone/surgical). These service components may be delivered directly as co-located services or as co-located and referral services to transgender persons who are not infected with HIV.

**Design**

An acceptable evaluation of a combination HIV prevention intervention for transgender persons who have sex with men will be one that measures the short- or longer-term effects of the intervention by comparing key outcomes measured prior to implementing delivery of the intervention with those measured after implementation of the intervention. Examples of acceptable evaluation designs include, but are not limited to:

- Pre-test and post-test assessment of the combination intervention without a comparison condition.
- Use of a concurrent intervention and comparison condition.
- Use of an intervention and a wait-list comparison condition.

A. An application should submit an Evaluation Plan. The Evaluation Plan should be used to guide the implementation and evaluation of the locally-developed or locally-adapted combination HIV prevention intervention with fidelity and to a standard that ensures that the proposed evaluation activities have sufficient scientific rigor to identify intervention processes, quality, costs, and detect anticipated behavioral and other outcomes.

**The Evaluation Plan should include:**

1. An acceptable evaluation design for this FOA that minimally satisfies the design and outcome criteria outlined below.
2. Descriptions of anticipated behavioral, biological, and psychosocial outcomes.
3. Descriptions of the social/structural determinants of health-related factors that the combination intervention addresses (or proposes with evidence) in order to facilitate access and utilization of HIV services.
4. Procedures for collection and analysis of process evaluation data.
5. Guidance for the implementation of the proposed homegrown combination intervention for transgender persons who have sex with men during the study period, including recruitment and retention of new participants.
6. Quality assurance measures to ensure that the homegrown combination HIV prevention intervention is delivered with fidelity by well-trained and qualified staff, including a logic model that specifies intervention components or activities and the outcomes expected for each component.
7. If the combined HIV prevention intervention includes a component that addresses the linkage and retention in care (LRC) of HIV positive transgender participants, these LRC components should meet published criteria for evidence-informed best practices for improving linkage and retention in HIV care as described by the CDC at [http://www.cdc.gov/hiv/prevention/research/compendium/lrc/bestpractices.html](http://www.cdc.gov/hiv/prevention/research/compendium/lrc/bestpractices.html).

The design for the proposed evaluation should minimally include the following elements:

- **Study Design**
  - Evaluates data before and after implementation in studies without a comparison arm.
- **Study Implementation and Analysis**
  - For pre-post intervention changes, analysis based on a 2-sided test with a p value of <0.05.
  - A sample size of approximately 40 participants.
- **Strength of Evidence**
  - Statistically significant (p <0.05) positive pre-post intervention effect for ≥ 1 relevant outcome measure.
  - No statistically significant negative pre-post intervention effect for any relevant outcome or no other statistically significant harmful intervention effect that causes substantial concern.

An application may propose an evaluation design with stronger evidence. The following elements are examples of stronger evidence:

- **Study Design**
  - Prospective or quasi-experimental design.
  - Appropriate and concurrent comparison arm, or appropriate non-concurrent comparison arm that was implemented in a different clinic or agency within 12 months of the start of the intervention and was similar with respect to population and setting.
  - Random allocation of participants to study arms or if non-randomization, potential bias in allocation to intervention is minimized.
- **Study Implementation and Analysis**
  - Comparison between intervention arm and an appropriate comparison arm.
  - At least a 6-month post-intervention follow-up assessment for each study arm (with recall referring to post-intervention period only).
    - For linkage to care interventions, that linkage to care occurred within or less than 6 months after the initiation of the intervention.
    - For retention in care interventions, that retention in care (e.g., at least 2 HIV care visits) occurred in a 6-month or longer time period after the initiation of the intervention.
  - Analysis of participants in study arms as originally allocated.
  - Analysis of participants may be based on intervention exposure, where participants exposed to < 50% of the entire intended intervention may be excluded.
  - Analysis must be based on between-group comparisons on post-intervention levels or on
pre-post changes in measures.

- For pre-post changes used in analysis, measures must be identical, including identical recall period.
- Analysis must be based on a 2-sided test with a p value of <0.05.
- With nonrandomized assignment, either no statistical differences exist in baseline levels or the biases assignment of historical comparison was used, differences in baseline demographics also must be controlled for.
- A sample size of at least 40 participants per study arm at each follow-up assessment.

**Strength of Evidence**

- Statistically significant (p < 0.05) positive pre-post intervention effect for ≥ 1 relevant outcome measure.
- No statistically significant negative pre-post intervention effect for any relevant outcome or no other statistically significant harmful intervention effect that causes substantial concern.

B. An application should submit a Qualitative Assessment Plan. The application should submit a plan that provides sufficient detail on how they will assess the intervention and related outcomes and describes how the combination HIV prevention intervention activities impacted HIV risk or participation in HIV care where applicable, and addresses social determinants of health for transgender persons. The qualitative assessment should include appropriate methods for qualitative inquiry that include but are not limited to, in-depth or semi-structured interviews with at least 30 intervention participants and staff; documentation of intervention delivery and integration of services; and structured observations of agency or clinic physical and policy environments.

During the project period, each grantee will:

- Year 1: Develop and submit a comprehensive protocol for local and CDC IRBs, and other reviews and approvals as needed; pilot-test assessment instruments to be used for the evaluation;
- Year 2: Implement the homegrown combination HIV prevention intervention; conduct the qualitative assessment and evaluation plan;
- Year 3: Continue to implement the homegrown combination HIV prevention intervention, conduct the evaluation plan, including any follow-up assessments;
- Year 4: Complete remaining follow-up assessments or data collection activities, conduct data cleaning and data analyses, and disseminate the findings.

**Target Population**

Transgender persons who have sex with men at high risk for HIV infection and in need of HIV prevention and other services; or transgender persons who have sex with men who are living with HIV and in need of HIV care and treatment and other services.

**Collaboration/Partnerships**

The application should have their own locally-developed or adapted combination HIV prevention intervention for transgender persons who have sex with men or should partner with a community-based organization (CBO), community health center (CHC) or other community-based service organization (CSO) who has locally-developed or adapted a combination HIV prevention intervention for this target population. If partnering with a CBO, CHC or CSO, the application should provide documentation of its prior successful experiences collaborating with the partnering organization, and a representative of the partner organization should have a substantial role on the project, such as Co-Principal Investigator.

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

The application should include:

Collection and analysis of the following process evaluation data:

- Characteristics of participants.
- Number and content of activities delivered to and completed by participants.
- Resources used to deliver the intervention (including basic costs associated with delivering the intervention).
- Modifications made to the intervention.
- Participant perceptions of and reactions to intervention activities and services provided.

Collection and analysis of the outcome evaluation data from approximately 40 participants:

- Pre- and post-intervention biological, behavioral, psychosocial assessments.
- If using a comparison arm, a 6-month follow-up assessment of biological, behavioral, psychosocial outcomes.
- For linkage and retention in care interventions, length of time between when retention in care occurred and when the intervention was initiated.

A qualitative assessment of intervention implementation experiences with a total of at least 30 participants and implementing staff.

Collection and analysis of the following qualitative assessment data from at least 30 intervention participants and staff:

- Intervention delivery process as it relates to each associated outcome.
- Integration of services.
- Agency or clinic physical environment.
- Agency or clinic policy environment.

**Translation Plan**

The application should propose a plan for: a) using the existing intervention manuals and materials that are required in support of its application as the basis for developing materials for the eventual dissemination of the combined intervention, and b) using process and outcome data obtained during the proposed evaluation if the combined intervention is determined to be effective, to refine or improve the existing manuals, materials, and other formal documentation needed to demonstrate to other service provider organizations how to best implement the combined HIV prevention intervention for transgender persons who have sex with men.

**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:** $3,600,000

**Anticipated Number of Awards:** 2

The ceiling of $200,000 is for the first 12-month budget period for an individual award; funds available in the first 12-month budget period are estimated to be $400,000 for two awards ($200,000 for each award).

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

**Award Ceiling:** $200,000 Per Budget Period

**Award Floor:** $0 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

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

Additional Eligibility Category:

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

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

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

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

Other:

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

Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=512ff78311f427c00454772dcf21523a&rgn=div8&view=text&node=48:1.0.1.6.34.0.1.18&idno=48

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements
Additional Information on Eligibility

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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

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

- If the applicant is partnering with a service providing organization (CBO, CHC, or CSO) that developed a combination HIV prevention intervention for transgender persons who have sex with men, the applicant must provide a Letter of Support from the partnering organization giving the applicant permission to conduct the project and agreeing to collaborate in the implementation of the intervention, and the collection, analysis, write up, and presentation of qualitative, process and quantitative outcome data during the entire project period.

- The application must include a statement from the applicant or the partner organization that the homegrown combination HIV intervention is not an intervention already listed on the CDC’s Compendium of HIV Prevention Interventions website (http://www.cdc.gov/hiv/prevention/research/compendium/index.html) and that the intervention is not delivered to students as part of a school-based curriculum.

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
- eRA Commons

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

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](https://www.usbusiness.net/duns/request.jsp) 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](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](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](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

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

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from [www.Grants.gov](http://www.Grants.gov). If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or [pgotim@cdc.gov](mailto:pgotim@cdc.gov) for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at TTY 1-888-232-6348.
2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

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

3. Letter of Intent

Due Date for Letter of Intent: 01/12/2016

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

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

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

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
Telephone: 404-718-8833
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.**

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.

Applicants should include the following documentation in the Appendices:

1) Written curricula and/or implementation guides or manuals; standard operating procedures or policies; or internal written documentation of intervention activities used to deliver each component of the homegrown combination HIV prevention intervention.

2) Evidence that the applicant, or the partnering organization, can recruit a sufficient number of transgender persons who have sex with men for the proposed research activities, such as the number of clients participating in agency programs or services. For an evaluation proposing a pre- and post-test design, the minimum sample size should be 40 participants. For an evaluation proposing a comparison arm, the minimum sample size should be 40 participants per arm.

3) Evidence that intervention activities have been developed or adapted with substantial input from the served community of transgender persons who have sex with men, such as written support and a description of contributions from community members.

4) Evidence that the intervention components address at least one social determinant of health relevant for transgender persons who have sex with men, which should be provided in the intervention curriculum or description OR evidence (from user feedback, process evaluation data) that the integration of at least one social/structural intervention component will improve access to and utilization of existing HIV prevention and care interventions for transgender persons who have sex with men.

5) Evidence that the intervention has been delivered to transgender persons who have sex with men during routine service delivery for a minimum of three consecutive years prior to the publication date of this FOA, such as client logs or records of services received (these must not include any personally identifying information).

6) Evidence that data have been collected suggesting that the combined intervention is potentially effective for reducing HIV-related risk behaviors or improving HIV care and treatment outcomes for transgender persons who have sex with men, such as user feedback or process evaluation data.

7. Page Limitations

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

8. Format for Attachments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### 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](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf).

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

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

Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services. Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget. Reimbursement of pre-award costs is not allowed.

Other than for normal and recognized executive-legislative relationships, no funds may be used for:

- Publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body;
- The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body.


Funds may **not** be used for PrEP or nPEP medications (e.g., Truvada), laboratory testing related to PrEP or...
nPEP (for example, creatinine tests, liver function tests, pregnancy tests, and other clinical tests that could result from evaluation of side effects/toxicities) or personnel costs for the provision of PrEP or nPEP medication and recommended clinical care associated with PrEP or nPEP.

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

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

12. Other Submission Requirements and Information

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. PAPER APPLICATIONS WILL NOT BE ACCEPTED. Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

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

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

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization’s profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide. If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters “FWA” before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement. See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/Electronic_Receipt/avoiding_errors.htm or http://grants.nih.gov/grants/Electronic_Receipt/submit_app.htm

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

Section V. Application Review Information
1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

Are the proposed study activities likely to have a positive impact on HIV prevention for the proposed target population?

Is the proposed target population at high risk for acquiring or transmitting HIV, including current social determinants of health, cultural and social norms, and risk behaviors for acquisition or transmission of HIV?

Is the proposed HIV intervention based on behavioral and/or social theory and does it aims to reduce HIV or STD risk and improve overall health outcomes in the target population?

Does the application include an intervention eligible to be considered for this FOA? (See Section I.1. Background and Purpose for the interventions that are not eligible for this FOA.)

Investigator(s)

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

Does the applicant demonstrate an understanding of the research objectives of this announcement as evidenced by the quality of the proposed research plan and specific study design?

Does the investigator provide evidence of having a thorough understanding of behavioral and biomedical HIV prevention, care, and treatment approaches?

Does the investigator have experience conducting research with the proposed target population?

Does the investigator and/or its partner organization have experience providing services that address social and structural determinants of health for transgender persons?

Does the investigator and/or its partner organization personnel have experience providing behavioral
prevention interventions and programs for transgender persons?

Does the investigator have experience evaluating health programs?

Does the investigator and/or its partner agency personnel have the ability to collect, manage, and analyze accurate data in a timely manner?

Does the investigator and/or its partner organization personnel have the appropriate training and skills to implement culturally relevant HIV prevention, care, and treatment interventions with the proposed target population?

If partnering with a CBO, CHC or CSO, does a representative of the partner organization have a substantial role on the project, such as Co-Principal Investigator?

Does the application document that the investigator, or the partnering CBO, CHC or other organization personnel, if applicable, has been delivering the locally-developed or adapted combination intervention to transgender persons who have sex with men for at least three years prior to the publication date of this announcement?

Innovation

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

Does the application propose a locally developed or locally adapted culturally appropriate approach to HIV prevention for the target population?

Does the application describe all components and activities of a locally-developed or adapted combination HIV prevention intervention?

Does the application describe how the locally-developed or adapted HIV prevention intervention was developed with substantial input from the transgender community served by the partner CBO, CHC or other organization?

Does the application demonstrate how the locally-developed or adapted intervention show promise as an evidence-informed or best practice intervention by presenting process data that can be directly attributable to the intervention?

Does the application document that the locally-developed or adapted combination intervention has never been and is currently not being systematically evaluated?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
Does the application demonstrate that the locally-developed or locally adapted combination HIV prevention intervention is appropriate for transgender persons?

Does the application include copies of the standard operating procedures, guidelines, curriculum, manual, or other written materials as Appendices to the application?

Does the application document that the applicant has obtained all relevant agreements and permissions from partnering organizations as necessary to implement and systematically evaluate the locally-developed or locally adapted combination HIV prevention intervention for the duration of the project?

Does the investigator or the partner organization document that the intervention being proposed for evaluation is not listed in the CDC Compendium, and is not delivered to students within a school-based curriculum?

Does the application describe how the applicant or the partner organization will gain access to sufficient numbers of the selected target population to successfully conduct the proposed research activities, as outlined in Part 2, Section I.2 Design?

Does the application include an Evaluation Plan to guide the implementation and evaluation of the locally-developed or locally-adapted combination HIV prevention intervention with fidelity and to a standard that ensures that the proposed evaluation activities have sufficient scientific rigor to identify intervention processes, quality, costs, and detect anticipated behavioral and other outcomes?

Does the Evaluation Plan include an Intervention Logic Model?

Does the application describe procedures for collecting, analyzing, and using quality assurance data to ensure that the approach is delivered with fidelity to the program logic model?

Does the application describe an outcome evaluation design that meets the criteria listed in Section I.2. Research Objectives?

Does the application provide a Qualitative Assessment Plan that provides sufficient detail on how the investigators will assess the intervention and related outcomes and describe how the combination HIV prevention intervention activities impact HIV risk or participation in HIV care, where applicable, and address social determinants of health for transgender persons?

Does the application provide plans for recruitment and outreach to study participants from the proposed target population?

Do the proposed activities recognize and address the diversity among members of the proposed target population?

Does the application sufficiently describe a process for sharing all data collected with the funding agency and other collaborating partners?

Will sufficient protection procedures be in place to ensure data security?

Is the proposed timeline sufficiently detailed, complete, and realistic for a 4-year project period?

Does the application provide a plan for developing and refining materials for the eventual dissemination of the combined HIV prevention intervention?

Does the application describe local HIV burden among transgender persons, as demonstrated by local HIV surveillance and other data?

Does the application address all of the components of this study listed in Part II. Section I?

Does the application include the required appendices listed under Section IV.6. Appendix?

Does the application include copies of all materials or procedures (curricula and/or facilitator guides or manuals; written standard operating procedures or policies, guidelines, or other written materials or data to
document activities) used by the applicant/partner organization to deliver the combination intervention?

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?

Is there evidence of institutional support for the application, alone or with a partner organization, to implement, evaluate, and potentially refine for dissemination the combined intervention?

Will the planned location for the study provide access to adequate numbers of transgender persons who have sex with men?

Does the application provide an adequate timeline for conducting the research?

Does the application include qualified personnel with realistic and sufficient percentage-time commitments relative to each phase of the study timeline?

Does the application provide adequate funds to the partner organization to implement the combination HIV prevention intervention during the study period?

Does the application provide a description of duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research?

How adequate are the plans for facilities, equipment, assessment programming, data processing, analysis capacity, and procedures for management of data security and participant confidentiality in order to achieve the research objectives?

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

Does the application provide evidence that the applicant or partner organization developed the combination HIV prevention intervention for transgender persons who have sex with men with substantial input from the served community; has been delivering the intervention to transgender persons who have sex with men for a minimum of three years; has collected prior positive process evaluation data demonstrating fidelity, availability, and acceptability of the intervention; and that the intervention has not undergone a previous systematic evaluation?

Additional Review Criteria

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

Biohazards

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

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

For more information about this Policy and other policies regarding dual use research of concern, visit the
guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Documents/durc-
companion-guide.pdf

2. Additional Review Criteria

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

**Protections for Human Subjects**

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

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

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

**Inclusion of Women, Minorities, and Children**

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

**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

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 \textit{will not give scores} for these items, and should not consider them in providing an overall impact/priority score.

\textbf{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: \url{http://www.cdc.gov/grants/additionalrequirements/index.html}. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

\textbf{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: \url{http://www.cdc.gov/grants/interestedinapplying/applicationresources.html}

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

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

- Will receive a written critique.

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

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

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

\section*{Section VI. Award Administration Information}
1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

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

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements
AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-7: Executive Order 12372 Review
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-17: Peer and Technical Reviews of Final Reports of Health Studies --; ATSDR
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Release and Sharing of Data
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”.
October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR 31 - Distinguishing Public Health Research and Public Health Nonresearch
AR 32 –; FY 2012 Enacted General Provisions

ARs applicable to HIV/AIDS Awards:

AR-5: HIV Program Review Panel Requirements
AR-6: Patient Care

The following are additional policy requirements relevant to this FOA:

Dual Use Research of Concern (DURC)

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

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

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

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

The following are additional policy requirements relevant to this FOA:

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

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

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. For the full text of the requirements, please review the following website: https://www.fsrs.gov.

Plain Writing Act

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

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

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

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

4. Cooperative Agreement Terms and Conditions of Award

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

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

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

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

- Developing all materials required for IRB submission (e.g., protocols, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed study and meet CDC IRB standards.
- Developing sampling and recruitment strategies to enroll adequate numbers of the proposed population of transgender persons who have sex with men who have not already been exposed to the combination HIV prevention intervention.
- Developing culturally sensitive quantitative measures of outcome variables that include, but are not limited to, behavioral outcomes such as condom use or frequency of unprotected sex, or biological outcomes such as sexually transmitted disease (STD) incidence.
- Developing stringent safeguards for protecting the rights and confidentiality of participants.
- Obtaining all necessary permissions and/or clearances to the study materials.
- Establishing an effective working relationship with a partnering organization, if applicable.
- Attending periodic meeting(s), as appropriate, at CDC and elsewhere to finalize the research protocol and provide progress updates.
- Implementing the locally-developed or adapted combination HIV prevention intervention.
- Identifying, recruiting, obtaining informed consent, enrolling and retaining an adequate number of participants in the research, as determined by the study protocols and the program requirements.
- Collecting all study data, including any laboratory tests that may be proposed.
- Ensuring data entry, security, and quality/accuracy.
- Analyzing data needed to evaluate the locally-developed or adapted combination HIV prevention intervention.
- Submitting all data collected to lead CDC Investigator over a secure data network.
- Implementing stringent safeguards and procedures for protecting the confidentiality of all research participants.
- When feasible, shared measures will be used and recipient organizations' site-specific information, data, and software developed under this award will be combined and made available for analyses by all
recipient organizations and CDC, subject to U.S. Government rights of access consistent with current
HHS and applicable HHS/CDC policies.
- Ensuring the protection of human subjects through ethical review of all protocols involving human
subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board
approvals for all institutions or individuals engaged in the conduct of the research project.
- Working with CDC scientists to obtain OMB-PRA approvals, as needed.
- PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced
under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for
example: “This publication (journal article, etc.) was supported by the Cooperative Agreement
Number above from the Centers for Disease Control and Prevention. Its contents are solely the
responsibility of the authors and do not necessarily represent the official views of the Centers for
Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or
manuscripts prior to any publication related to this funding. The grantee will not seek to publish or
present results or findings from this project without prior clearance and approval from CDC.
- Complying with the responsibilities for the PI as described in the United States Government Policy
- The direct and primary recipient in a cooperative agreement program must perform a substantial role
in carrying out project outcomes and not merely serve as a conduit for an award to another party or
provider who is ineligible.

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

- Conduct site visits to review preliminary intervention plans and evaluation design, and to assess the
commitment and capacity for implementation and evaluation of the proposed intervention by the
proposed collaborating agencies.
- Provide technical assistance, as needed, in program implementation, and the design and conduct of the
research.
- If CDC is engaged in the research, the CDC IRB will review and approve the protocol initially and on
at least an annual basis until the research project is completed.
- Conduct ongoing program monitoring of grantee implementation and evaluation activities.
- Monitor and evaluate scientific and operational accomplishments of this project through periodic
telephone contacts, site visits, review of technical reports, and interim data analyses. Based on this,
CDC will make recommendations aimed at solving problems and improving the quality and timeliness
of the research activities.
- Preparing the paperwork necessary for submission of research protocols to the CDC Institutional
Review Board for review, as needed.
- Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
- Assisting the PI, as needed, in complying with the PI responsibilities described in the United States
Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC)

Areas of Joint Responsibilities include:

- Perform appropriate data analyses as determined by the study collaborators.
- Share all data and collaborate with other investigators to answer common research questions.
- Present and publish research findings, as warranted.
- Participate in periodic conference calls and meetings with collaborators.
- Establish procedures to maintain the rights and confidentiality of all study participants.
- Conduct data analyses with collaborators and present and publish research findings, if CDC’s
contribution merits.
• Collaborate 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.

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

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

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement. A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

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

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

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

A. Submission of Reports

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

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

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

**B. Content of Reports**

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

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

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

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

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

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

     - How will this project lead to improvements in public health?
     - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
     - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

New Budget Period Proposal:

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

2. Annual Federal Financial Reporting

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

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

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

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

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: [http://era.nih.gov/commons/](http://era.nih.gov/commons/). Organizations not yet registered can go to [https://commons.era.nih.gov/commons/registration/registrationInstructions.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.

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**Section VII. Agency Contacts**

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

**Application Submission Contacts**

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

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

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

**Program Official/ Scientific Research Contact**

Amy Yang, PhD  
Extramural Research Program Office  
Office of the Associate Director for Science  
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
1600 Clifton Road, MS E-60  
Atlanta, GA 30333  
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Fax: 404-718-8822  
Email: vdz9@cdc.gov

**Peer Review Contact**

Gregory Anderson, MPH, MS  
Extramural Research Program Office  
Office of the Associate Director for Science  
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
1600 Clifton Road, MS E-60  
Atlanta, GA 30333  
Telephone: 404-718-8833  
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Email: GAnderson@cdc.gov

**Financial/Grants Management Contact(s)**
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 247c), as amended.