Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

AMENDMENT I. NEW DUE DATES AND SPECIAL DATE - Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males

RFA-DP-15-007

Application Due Date: 03/06/2015

AMENDMENT I. NEW DUE DATES AND SPECIAL DATE - Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males

RFA-DP-15-007

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

AMENDMENT I. NEW DUE DATES AND SPECIAL DATE - Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males

Activity Code

U01

AMENDMENT 2 includes:

1. Information on streamlining review of applications was added to 4. Review and Selection Process.

2. Questions from potential applicants and CDC responses was added to Section VIII. Other Information; APPENDIX C: DP-15-007: Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males: cleared by February 13, 2015

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-007

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

93.946

93.297

Category of Funding Activity:

Health

FOA Purpose

A collaborative initiative between the HHS Office of Adolescent Health (OAH) and the Centers for Disease Control and Prevention (CDC), the purpose of this research opportunity is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy and that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). Up to three 5-year research projects will be funded, with at least one project evaluating an intervention targeted at young men aged 15-19 years.

Applicants will be funded as either Component A or B grantees, based on the readiness of the intervention to be rigorously evaluated. Component A applicants will submit a proposal using an existing intervention that has promising process data and/or some evidence of effectiveness, but that has not been rigorously evaluated. Component B applicants will submit a proposal using a partially developed intervention to be finalized prior to evaluation.

Both Component A and Component B projects will rigorously evaluate the interventions with an experimental approach, package efficacious interventions, and provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes,

and to authorize others to do so in accordance with applicable grant regulations (Part I).

Both Component A and Component B applicants will also obtain and conduct training and/or technical assistance (TTA) activities and services tailored to grantees' needs to ensure high-quality implementation and rigorous evaluation of the proposed interventions (Part II).

Key Dates

Publication Date: **To receive notification of any changes to RFA-DP-15-007, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**

Letter of Intent Due Date: **02/06/2015**

AMENDMENT I.
New Letter of Intent Due Date: February 6, 2015

Application Due Date: **03/06/2015**

AMENDMENT I.
Application Due Date has been changed from March 3, 2015 to March 6, 2015

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: **04/01/2015**

Secondary Review: **05/05/2015**

Estimated Start Date: **09/30/2015**

Expiration Date: **03/07/2015**

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

Required Application Instructions

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

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

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

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

Executive Summary

- **Purpose.** A collaborative initiative between the HHS Office of Adolescent Health and the Centers for Disease Control and Prevention, the purpose of this research opportunity is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). Up to three 5-year research projects will

be funded, with at least one project evaluating an intervention targeted at young men aged 15-19 years.

- Projects will be funded under either Component A or B, based on the readiness of the intervention to be rigorously evaluated. Applicants will submit a proposal using either: A) an existing intervention that has promising process data and/or some evidence of effectiveness, but has not been rigorously evaluated; or B) a partially developed intervention to be finalized prior to evaluation.
- Component A and Component B projects will rigorously evaluate the interventions with an experimental approach, package efficacious interventions, and provide CDC and OAH with final intervention package materials , to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations. In this FOA, the set of activities on evaluation is referred to as Part I.
- Component A and Component B projects will also obtain and provide training and technical assistance (TTA) that is tailored to the needs of the grantee (internal TTA) and the grantee's external partners (external TTA) to ensure high-quality implementation and rigorous evaluation of the proposed interventions. In this FOA, the set of activities on training and technical assistance is referred to as Part II.
- Component A and Component B applications must address both Part I and Part II activities to be considered responsive.
- **Mechanism of Support.** The funding mechanism is a cooperative agreement.
- **Funds Available and Anticipated Number of Awards.** Funding used for selected research projects will enhance knowledge and evidence regarding effective approaches for working with young men to prevent and reduce teen pregnancy. The estimated total funding, covering both direct and indirect costs for the entire project period, for Component A and Component B combined, is $10,000,000. The intent is to commit a total of approximately $2,000,000 (direct and indirect) for the first 12-month budget period for two (2) to three (3) 5-year research projects, with at least one project evaluating an intervention targeted at young men aged 15-19 years. Two to three grantees will be awarded $666,000 to $1,000,000 (direct and indirect) costs in FY2015. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size of each award may vary. The total amount awarded and the number of awards will depend upon the number, quality, and cost of the applications received. However, the total number of grantees will not exceed three and the total funding amount will not exceed $2,000,000 in FY2015. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications.
- **Funding Source**: This FOA is funded by the HHS OAH Teenage Pregnancy Prevention Program (OAH) and the CDC Safe Motherhood Program (CDC). Part I activities are supported by OAH and Part II activities are supported by CDC. Projects will be funded either as Component A or B grantees, and will be funded with a combination of both Part I (OAH) and Part II (CDC) funds. Specifically, grantees will be awarded Part I funds of $533,000 to $800,000 plus Part II funds of $133,000 to $200,000 for combined direct and indirect costs in FY2015.
- Because awardees will be funded with two sources of funds, applicants are expected to submit a single budget, but that budget must delineate and distinguish Part I and Part II activities and related planned expenditures.
- **Budget and Project Period.** The estimated total funding, covering both direct and indirect costs for the entire project period, for Component A and Component B combined, is $10,000,000. Part I funds will include up to $8,000,000 in funds from OAH that are available for two to three research projects for up to 5 years, with at least one project evaluating an intervention targeted at young men aged 15-19 years. Part II funds will include up to $2,000,000 in funds from CDC that are available for to the Component A and B awardees for training and/or technical assistance (TTA) activities and services that help ensure high-quality implementation and rigorous evaluation of the proposed interventions. The project period will run from 09/30/2015 to 09/29/2020.
- The total funding (direct and indirect for the first year [12-month budget period]) is approximately $2,000,000 for Part I and Part II activities. Total Part I OAH funding (direct and indirect) for the first year (12-month budget period) is approximately $1,600,000. Total Part II CDC funding (direct and

indirect) for the first year (12-month budget period) is approximately $400,000. The first year of the project period will run from 09/30/2015 to 09/29/2016.

- **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.A. 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.** Applications may contain more than one PI, however, the first PI listed will be the "contact PI" for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct.
- **Application Type.** New
- **Special Date.** CDC will conduct one teleconference for prospective applicants. This session will provide information about the FOA and will answer questions pertinent to preparing applications in response to this FOA.
    - Teleconference Date: January 14, 2015 at 1:00 p.m. (EST)
    - Call-in Number: 1-877-985-9419
    - Participant Passcode: 773482

    NEW - A second teleconference for prospective applicants has been scheduled:

    * Teleconference Date: January 26, 2015 at 1:00 p.m. (EST)

    * Call-in Number: 1-800-369-1782

    * Participant Code: 1980059
- **Application Materials. See Section IV.1 for application materials.**
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.
- This FOA will be posted at http://www.cdc.gov/chronicdisease/about/foa.htm

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Division H, Title II of the Consolidated Appropriations Act, 2014 (Public Law No. 113-76), and the Continuing Resolution thus far for FY 2015 (Public Law No. 113-164), and Section 317K and 301(a) of the Public Health Service Act, 42 U.S.C. 247b-12, 241(a).

Office or Management and Budget (OMB) Paperwork Reduction Act (PRA) requirements are expected to apply.

1. Background and Purpose

Although teen birth rates (defined as live births per 1,000 15–19 year-old U.S. females) are declining, nearly 275,000 infants were born to teen mothers aged 15–19 years in 2013 (Hamilton, 2014), and the U.S. teen birth rate remains higher than in other developed countries (Penman-Aguilar, Carter, Snead, & Kourtis, 2013). Furthermore geographic, socioeconomic, and racial/ethnic disparities in teen birth rates persist. In 2012, non-Hispanic black and Hispanic teen birth rates were still more than two times higher than birth rates for non-Hispanic white teens (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013).

Most pregnancies among female teens (82%) are unintended (Finer and Zolna 2014), and teen pregnancy and childbearing may bring substantial social and economic costs through immediate and long-term impacts on teen mothers and their children. Only about 50% of teen mothers receive a high school diploma by 22 years of age, versus approximately 90% of women who have not given birth during adolescence (Perper, Peterson, & Manlove, 2010). Children born to teen mothers experience poorer health and lower academic achievement, higher rates of teen pregnancy for female children, and higher rates of incarceration for male children (Hoffman 2008).

In 2012, teen fatherhood occurred at a rate of 13.8 births per 1,000 men aged 15-19 (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013) and resulted in approximately 156,000 births. According to the 2002 National Survey of Family Growth, 15% of males fathered a child while under the age of 20 and rates were highest among non-Hispanic Black and Hispanic teens (Martinez, Chandra, Abma, Jones, & Mosher, 2006). Data suggest that teen fathers attend fewer years of school and are less likely to graduate from high school (Fletcher & Wolfe, 2012). In addition, males just beyond their teen years (aged 20-24) father a higher proportion of children born to teen mothers than males aged 19 and younger (Elo, King, & Furstenburg, 1999; Males, 1995). Thus, it is important to reach both teenage as well as young adult males in their early 20s (hereafter referred to as "young men") in teen pregnancy prevention efforts. Although typically teen pregnancy is defined by the age of the mother, for the purposes of this FOA, we are interested in those young men at risk of fathering a teen pregnancy, i.e., either teen males who father a pregnancy or men beyond their teen years who father a pregnancy to a female teen.

Initiatives to prevent teen pregnancy have focused primarily on the role of female teens; however, as described above, young men can also play an important role in preventing teen pregnancy and should be actively engaged in pregnancy prevention efforts. Partner involvement in contraceptive decision making has been shown to increase use of effective methods of pregnancy prevention, including the use of dual protection (i.e., the use of condoms plus hormonal methods for the prevention of pregnancy and sexually transmitted infections [STIs]) (Kerns 2003, Harper 2004, Kraft 2010, Cox 2010). This influence may be based on higher levels of contraception-related communication, joint responsibility, and decision-making between partners, as well as male partners' knowledge and attitudes about contraceptive methods (including condoms), support for use of moderately or highly effective methods, and desire for pregnancy prevention. These and other mediators can be addressed in interventions for males, which is why it is so important for this funding opportunity to study initiatives designed to focus on young men. Despite the important role of the male partner in teen pregnancy prevention, working with young men is an underused approach to teen pregnancy prevention (TPP).

Implementing evidence-based interventions (EBI) for sexual risk reduction in clinical and community settings is a significant teen pregnancy prevention strategy supported by the Centers for Disease Control and Prevention (CDC) and the HHS Office of Adolescent Health (OAH) (OAH; U.S. Department of Health and Human Services, 2012). Yet, there are few interventions that are designed specifically for young men and that have been shown to be effective in reducing teen pregnancy. A systematic review (http://tppevidencereview.aspe.hhs.gov/ReviewProtocol.aspx)conducted in 2012 by Mathematica Policy Research (U.S. Department of Health and Human Services, 2012) and updated in 2014, identified 35 rigorously evaluated interventions found to have an impact on sexual risk behaviors, teen pregnancy, and/or STIs, known as the HHS Teen Pregnancy Prevention Evidence Review http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx (hereafter referred to as the "Evidence Review"). Most of these interventions included male and female participants, with only one intervention designed specifically for males (Magura, Kang, & Shapiro 1994).

These interventions were typically designed as HIV/STI prevention interventions and provide participants with information about condoms, but offer them little information about other contraceptive options. These interventions typically lack a focus on the shared responsibility of contraceptive decision making or on sexual and reproductive health services. Interventions exist that focus on male-specific risk and protective factors for teen pregnancy (e.g., Gottesgen & Philiber, 2001; Ricardo, Nascimento, Fonseca & Segundo, 2010; Smith, Weinman, Buzi, & Benton, 2004; Tello, Cervantes, Cordova, & Santos, 2010), but results from rigorous evaluations of these interventions have not been reported in the peer-reviewed literature.

Purpose:

A collaborative initiative between the HHS Office of Adolescent Health (OAH) and the Centers for Disease Control and Prevention (CDC), this research opportunity is a part of HHS-funded research and demonstration activities to support the evaluation of innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy. Interventions should target young men at high risk of fathering a teen pregnancy (e.g**.,** young men at risk of health disparities due to low socioeconomic status (SES), race/ethnicity [with respect to high pregnancy rates among female teens who are Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander, American Indian and Alaska Native], exposure to social determinants negatively affecting health [e.g., inadequate housing, lower educational attainment, stressful neighborhood environment, high community unemployment, etc.], being out of school [for young men under age 18], unemployment [for young men ages 18-24], living in foster care, homelessness, experiencing trauma or domestic violence, involvement with the criminal justice system, substance abuse) (Adapted from CDC Office of Minority Health and Health Equity, HHS Office of Adolescent Health, and John Snow, Inc.). Interventions should primarily focus on a selected age group within the ages of 15 through 24 years (e.g., young men in high school; young men ages 20-24). Projects will test innovative interventions designed for males that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

The following is a summary of the application structure:

Structure and Required Elements for Component A and Component B Applications	
Component A (Existing Intervention)	**Component B (Partially Developed Intervention)**
• Part I (implementation and evaluation)	• Part I (implementation and evaluation)
• Part II (training and technical assistance)	• Part II (training and technical assistance)

Applicants will be funded as either Component A or Component B grantees, based on the readiness of the intervention to be rigorously evaluated. Component A applicants will submit a proposal using an existing intervention that has promising process data and/or some evidence of effectiveness, but that has not been rigorously evaluated. Component B applicants will submit a proposal using a partially developed intervention to be finalized prior to evaluation. Both component A and Component B projects will rigorously evaluate the interventions with an experimental approach, package efficacious interventions, and provide CDC and OAH with final intervention package materials, to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations.

Component A: Applicants for Component A will have an existing intervention that:

a) Is implementation-ready (although the intervention materials may need some minor editing before conducting a rigorous evaluation) and has been implemented in its entirety at least once (and preferably many times) in one or more settings; and

b) Has promising process data (e.g., feasibility and acceptability among the target population and setting) and/or some evidence of effectiveness (e.g., pre-posttest findings of increased intention to use condoms

and/or highly or moderately effective contraception, increased knowledge of contraceptive methods, increased partner communication self-efficacy regarding contraceptive use, etc.), but has not been rigorously evaluated (i.e. randomized controlled trial or non-randomized design with external comparison group) to date.

Component B: Applicants for Component B will have a partially developed intervention to be completed prior to the evaluation. Successful applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

Component A and Component B projects will address two sets of activities:

- **Part I: Implementation and Evaluation.** Applicants will rigorously evaluate the interventions with an experimental approach, package efficacious interventions, and provide CDC and OAH with final intervention package materials, to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations.
- **Part II: Training and Technical Assistance.** Applicants will also conduct training and technical assistance (TTA) that is tailored to the needs of the grantee (internal TTA) and the grantee's external partners (external TTA) to ensure high-quality implementation and rigorous evaluation of the proposed interventions. Applicants for both Component A and Component B may propose to use Part II funds toward internal, external, or a combination of internal and external training and technical assistance, depending on the needs of the grantee.

Applicants for Component A must address both Part I and Part II activities to be considered responsive to the intent of this FOA.

Applicants for Component B must address both Part I and Part II activities to be considered responsive to the intent of this FOA.

Applicants funded under this FOA, whether Component A or Component B, must acknowledge receipt of funds from the two funding sources, OAH and CDC, and must address budget requirements to delineate and distinguish Part I and Part II activities and expenditures.

Healthy People 2020 and other National Strategic Priorities

This program addresses the Healthy People 2020 overarching goal for disparities (to achieve health equity, eliminate disparities, and improve the health of all groups) as well as the focus areas of family planning, sexually transmitted diseases and HIV:

1) FP-6 Increase the proportion of females at risk of unintended pregnancy or their partners who used contraception at most recent sexual intercourse.

2) FP-7 Increase the proportion of sexually experienced persons who received reproductive health services.

3) FP-8 Reduce pregnancies among adolescent females.

4) FP-11 Increase the proportion of sexually active persons aged 15 to 19 years who use condoms and hormonal or intrauterine contraception to both effectively prevent pregnancy and provide barrier protection against disease.

5) STD-1: Reduce the proportion of adolescents and young adults with chlamydia trachomatis infections.

6) STD-6: Reduce gonorrhea rates.

7) HIV-1: Reduce the number of new HIV diagnoses among adolescents and adults.

This research opportunity is aligned with My Brother's Keeper (http://www.whitehouse.gov/my-brothers

-keeper), a White House initiative to address persistent opportunity gaps faced by boys and young men of color, and the White House Fatherhood Initiative and Mentoring Initiative (http://www.whitehouse.gov/champions/fatherhood). It supports the National Prevention Strategy (i.e., recommendations for Elimination of Health Disparities and for Reproductive and Sexual Health); the CDC Winnable Battle areas of Teen Pregnancy http://intranet.cdc.gov/od/winnablebattles/teenpregnancy and HIV and the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) priorities of increasing health equity and conducting research. The research to be conducted addresses the Division of Reproductive Health priorities of *Unintended Pregnancy Prevention* and *Women's Reproductive Health* and two key strategic areas of focus within these priorities: *Teen Pregnancy Prevention* and *Family Planning Methods, Services, and Use*.

This funding opportunity announcement is one of a series of five funding opportunities, each with a different focus, available through the HHS Office of Adolescent Health's Teen Pregnancy Prevention Program. Applicants may apply for more than one FOA. This FOA provides information to apply for FOA RFA-DP-15-007– Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males. Other anticipated funding opportunity announcements from OAH include:

- Capacity Building to Support Implementation of Evidence-Based TPP Programs (OAH-15-0003)
- Implementing Evidence-Based Teen Pregnancy Prevention Programs to Scale in Communities with the Greatest Need (OAH-15-0004)
- Supporting and Enabling Early Innovation to Advance Adolescent Health and Prevent Teen Pregnancy (OAH-15-0006)
- Rigorous Evaluation of New or Innovative Approaches to Prevent Teen Pregnancy (OAH-15-0007)

Information about these anticipated FOAs is available from the HHS grant forecast which can be found at: http://www.acf.hhs.gov/hhsgrantsforecast/.

Public Health Impact

Through this announcement, HHS (OAH and CDC) intends to fund projects that have the potential to yield high-impact research results by reducing public health burden and improving population health. This work will expand on a limited research base by providing much needed investigation on how to develop, implement, and evaluate interventions related to teen pregnancy prevention and sexual and reproductive health for young men. The research also has the potential to expand evidence-based TPP and sexual and reproductive health interventions, thereby increasing the arsenal of strategies to reduce risk behaviors and improve sexual and reproductive health for young men and their female partners, and reduce unintended and teen pregnancy in the United States.

Relevant Work

Refer to *Background and Purpose* section.

2. Approach

The project goal is to increase the number of evidence-based TPP interventions for 15-24 year-old young men at high risk for fathering a teen pregnancy and make such interventions available to the broader field to use in their public health efforts. To meet this goal, grantees will rigorously evaluate either an existing intervention that has not been rigorously evaluated (Component A) or a partially developed intervention to be finalized prior to evaluation (Component B). Through research and intervention implementation activities, the announcement also aims to expand the knowledge base on developing, implementing, and evaluating TPP interventions for young men.

Objectives/Outcomes

Part I. Implementation and Evaluation

Component A applications must identify an existing intervention that has promising process data and/or some **evidence** of effectiveness, but has not been rigorously evaluated. Component B applications must identify a partially developed intervention to be finalized prior to evaluation. Component A and B applications must include a summary of the intervention; a logic model (including: the intervention goals and objectives and the intervention's theoretical basis); the age range of participants and the target population; and a summary of all completed intervention materials (or draft materials for Component B), including implementation manual(s). Applicants are encouraged to provide all intervention materials as page limits for the Appendices permits.

Interventions that are **not** acceptable for this funding announcement include those already included as an evidenced-based program as determined by the Evidence Review; those in CDC's Compendium of Evidence-Based Risk Reduction Interventions for HIV Prevention *(*http://www.cdc.gov/hiv/prevention/research/compendium/rr/complete.html); those currentlyundergoing a rigorous evaluation under funding opportunity announcement OPHS/OAH-TPP PREP Tier2-2010 *(*http://www.hhs.gov/ash/oah/news/assets/funding_announcment_research.pdf); or those that replicate or make changes (adaptations) to these interventions (See a complete list in FOA Appendix A).

The proposed intervention should be targeted to young men within the age range of 15-24 years who are at high risk for fathering a teen pregnancy and should fill a significant gap in evidence-based TPP interventions (e.g., critical target populations and/or settings that are not reached by existing interventions). Interventions must be developed with significant input from the target population and based on theoretical models to innovatively address the unique risk and protective factors associated with fathering a teen pregnancy. Interventions may address factors at the individual, interpersonal relationship, community, structural, or multiple levels to affect behavioral, clinical, or biological outcomes. Interventions must be feasible to implement in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings) during the project period and for future implementation in real-world settings. Applicants should explain how the proposed target setting(s) fit well with the intervention and target population and have the potential to reach large numbers of young men.

Applicants will ensure that program materials, including all materials associated with the intervention and any supplemental materials (i.e. curricula, facilitator and participant manuals, videos, podcasts, posters, scripts, participant booklets, pamphlets, and handouts) are medically accurate, complete, and age appropriate, and should ensure that all materials are culturally and linguistically appropriate, and sensitive to and inclusive of Lesbian Gay Bisexual Transgender and Questioning (LGBTQ youth). Interventions should be implemented in environments that are positive, safe, supportive, and healthy for all youth and their families. To ensure that the most current science is reflected in the intervention materials, successful applicants will be required to submit all intervention materials prior to use in the project to OAH for a medical accuracy review.

To ensure that the most current science is reflected in the intervention materials, successful applicants will be required to submit all intervention materials to be used in the project to CDC and OAH for a medical accuracy review. This review of intervention materials will be conducted after an application is approved for funding. The successful applicant will be notified of any content that needs modification and will make any necessary changes. The intervention materials may not be used in the project until after the medical accuracy review is final and any required modifications are made. The grantee must verify that all required modifications have been made and accepted by CDC and OAH.

Applicants must demonstrate capacity and experience accessing and working with large groups of young men, including evidence of successful enrollment in programs, intervention studies or trials, and the expertise to implement the intervention with fidelity and conduct a rigorous evaluation. Applicants may use partnerships to fulfill the capacity needs for successfully completing the project (e.g., intervention developer collaborating with a clinic and/or youth-serving organization to develop and implement the intervention;

partnering with a research firm to conduct the evaluation). The applicant PI(s) and their primary partners will hereafter be referred to as the Study Team. Such partnerships should be documented through written and signed agreements prior to application submission, and preferably have previous successful collaborations together. Applicants may also use Part II funds to increase the capacity of internal and external staff (see below). Applicants should engage stakeholders in the form of a community advisory board (CAB), which includes representation from the target population and target settings. The CAB should provide input throughout the project period to ensure that interventions resonate with the target population and are feasible to implement in the target setting. The CAB should also provide input on evaluation activities, such as participant recruitment and retention.

The awards under this funding opportunity are cooperative agreements, which require substantial federal programmatic involvement throughout the project period. This will include CDC's close collaboration with recipients to: ensure adherence to project aims; review and provide input on intervention and evaluation materials and study analyses; develop outcome-focused and other project-related manuscripts; review training and technical assistance plans; provide ongoing training, technical assistance, oversight, troubleshooting; and facilitate coordination with other agencies and offices within HHS. Recipients will submit all de-identified study data to CDC over a secure data network. As described above, recipients will also provide CDC and OAH with final intervention package materials.

All funded grantees will collect and report on a common set of performance measures to assess program implementation and whether the program is observing intended program outcomes. Performance measures must be collected for every participant (at the individual level) served by the project using non-identifying identification numbers. The broad categories of the measures that grantees are expected to collect and report includes reach, dosage of intervention (individual-level attendance), fidelity and quality, linkages and referrals to healthcare services, cost of implementing the program, sustainability, partnerships, trainings, and dissemination. Please refer to the detailed list of measures in Appendix B.

Applicants should review relevant state laws, school district policies, and other administrative procedures of their sites or partner organizations to ensure the feasibility of data collection. If necessary, applicants should obtain any required permissions to collect these data. Applicants should demonstrate/indicate within the application that they have permissions to collect these data and report them to CDC as part of this project, as well as demonstrate the capacity to do so at the individual level. There are no exceptions or waivers from this requirement.

Part II. Training and Technical Assistance

Component A and B applications must include a detailed description of a plan for training and technical assistance (TTA) that is tailored to the needs of the grantee (internal TTA) and the grantee's external partners (external TTA) to ensure high-quality implementation and rigorous evaluation of the proposed interventions. Applicants for both Component A and Component B may propose to use Part II funds toward internal, external, or a combination of internal and external training and technical assistance, depending on the needs of the grantee.

Part I.

Objective 1: Develop and prepare the proposed intervention for a rigorous evaluation. Below are some of the activities anticipated for objective 1.

Component A:

- Identify and convene a community advisory board (CAB)
- Refine and finalize intervention materials (as applicable) to prepare for the evaluation, including but not limited to a logic model, core elements, curricula, and training manuals
- Pilot test feasibility and appropriateness of intervention with target population and setting(s)

Component B:

- Identify and convene a community advisory board (CAB)
- Finalize intervention approaches and produce detailed intervention materials, including but not limited to a logic model, core elements, curricula, and training manuals
- Pilot test feasibility and appropriateness of intervention with target population and setting(s)

Objective 2: Evaluate the intervention. There will be two evaluation elements: a quantitative efficacy evaluation and a qualitative evaluation. Below are the parameters for the evaluation design and some of the anticipated activities for objective 2.

Components A and B:

- Develop and implement quantitative efficacy evaluation of the intervention
    - The proposed evaluation plan should address the required elements outlined in the Evidence Review (http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx) (see Appendix A for a summary). Evaluations implementing randomized controlled trials (RCTs) are preferred, though rigorous evaluations with non-randomized designs that include an external comparison group are acceptable when an RCT is not feasible. Cooperative agreement recipients and Study Team partners will receive training and technical assistance from CDC on developing and implementing research protocols that meet HHS evidence standards.
    - Applicants should provide a power analysis that demonstrates the proposed sample size after anticipated attrition is sufficient to detect an intervention effect, and that includes a sufficient post-intervention follow-up period to adequately assess outcomes of interest (at least 24 months for Component A and 12 months for Component B).
    - Evaluation outcomes
        - The primary outcomes to be assessed are increased: condom use; abstinence from vaginal intercourse (primarily for teen males); use of sexual and reproductive health services; female partners' use of moderately effective contraception (hormonal injection; patch; ring; pill) or highly effective long-acting reversible contraception (implant; IUD); and dual use of condoms and moderately or highly effective contraception. The applicant should address possible limitations in assessing outcomes related to female-controlled methods of contraception (i.e., moderately or highly effective contraceptive methods), since these methods are not under the direct control of the male intervention participants. Measures will need to be designed to maximize reliability.
        - Where possible, the evaluation should assess pregnancies and births among teen female partners and incidence of STIs among male participants
        - Key intermediate outcomes based on the intervention logic model should be assessed
    - Implementation of the evaluation should include process monitoring and quality assurance activities; protections of human subjects; baseline and follow-up data collection for intervention and comparison groups; and data security, cleaning, and analysis activities, including assessment of intervention efficacy.
- Develop and implement qualitative evaluation of the intervention
    - The purposes of a qualitative evaluation element are to provide context to the quantitative efficacy results and enhance understanding of intervention, such as the components that resonate with participants and mediate behavior change, barriers to behavior change and intervention attendance, and in-depth feedback on participants' experiences in the intervention. This evaluation element should also assess facilitators and barriers to program implementation, cost of implementing the intervention, and provide information to finalize intervention packaging. In addition, these data may provide valuable information to inform future efforts to develop and implement teen pregnancy prevention interventions for young men.
- Implementation should include process monitoring and quality assurance activities; data collection

procedures; and data security, cleaning, transcription, and analysis activities.

Objective 3: Develop and implement a plan to package efficacious interventions and disseminate study results and products. Below are some of the activities anticipated for objective 3.

Components A and B:

- Complete packaging of efficacious interventions
    - Use lessons learned from the quantitative and qualitative evaluations to refine intervention materials, including but not limited to: the logic model, implementation and training curricula, technical assistance guidance for implementation, information on the intervention's logistics and costs, and any process and outcome monitoring tools.
    - Prepare a package of the completed intervention that can be shared with other teen pregnancy preventions programs. The package should address required elements as outlined at: http://www.hhs.gov/ash/oah/oah-initiatives/for-grantees/program-guidance/Assets/tpp_packaging_guidance.pdf
- Prepare intervention outcome-related manuscript for submission to a peer-reviewed journal; Prepare manuscript and/or report on the findings from the qualitative evaluation

Part II.

Objective 4: Develop and implement a detailed plan for training and technical assistance (TTA) that is tailored to the needs of the grantee (internal TTA) and the grantee's external partners (external TTA) to ensure high-quality implementation and rigorous evaluation of the proposed interventions. Below are some of the activities anticipated for objective 4.

Components A and B:

- Develop a detailed internal and/or external training and technical assistance (TTA) plan.
    - Internal TTA refers to training and technical assistance that is delivered to the grantee or the grantee staff. Internal TTA could be provided by an expert member of the grantee staff, member of the Study Team, consultant, expert, or organization ("TTA providers").
    - External TTA refers to training and technical assistance that is provided to parties who are not part of the grantee's staff or Study Team. External TTA could be provided by an expert member of the grantee staff, member of the Study Team, consultant, expert, or organization ("TTA providers").
    - Examples of areas and types of consultation, technical assistance, and/or training that might be sought include, but are not limited to: designing, implementing, and packaging sexual health interventions and studies focused on young men; conducting randomized controlled trials in accordance with consolidated standards of reporting trials (CONSORT) guidelines; recruiting and retaining young male participants; strengthening a male focus in youth-serving intervention settings (such as clinics, schools, corrections facilities, etc.); training program, clinical, or other staff to implement interventions with fidelity; evaluating interventions targeting young men; and packaging these interventions for dissemination and scale up; or other identified TTA needs of the grantee.
- Implement CDC-approved TTA plan and conduct continuous assessment of internal and external capacity needs and tailor activities and TTA providers as needed.

Target Population

The target population for this project are young men within the age range of 15-24 years who are at high risk for fathering a teen pregnancy (e.g**,** ***young men at risk of health disparities due to*** low socioeconomic status (SES), race/ethnicity [with respect to high pregnancy rates among female teens who are Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander, American Indian and Alaska Native], exposure to social determinants negatively affecting health [e.g., inadequate housing, lower educational attainment, stressful neighborhood environment, high community unemployment, etc.], being out of school [for young men under age 18], unemployment [for young men ages 18-24], living in foster care, homelessness, experiencing trauma or domestic violence, involvement with the criminal justice system, substance abuse).

Collaboration/Partnerships

Grantees are expected to develop a Study Team to fulfill the capacity needs for successfully completing the project (e.g., intervention developer collaborating with a clinic and/or youth-serving organization to develop and implement the intervention; partnering with a research firm to conduct the evaluation). Grantees will establish and partner with a community advisory board (CAB), which includes representation from the target population and target settings. Grantees will also collaborate closely with CDC.

To ensure that the intervention tested is a significant step forward for the field and that the intervention and the evaluation are of the highest quality and rigor, Component A and Component B grantees are expected to collaborate with one or more TTA providers (such as internal or external consultants, organizations) that have the expertise and ability to provide needed technical assistance and training related to the proposed project.

Evaluation/Performance Measurement

All funded grantees are expected to complete a rigorous evaluation designed to address the required elements outlined in the Evidence Review (http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx) (see Appendix A for a summary), and a qualitative evaluation. All funded grantees will collect and report on a common set of performance measures to assess program implementation and whether the program is observing intended program outcomes. Grantees should consider whether TTA is needed to successfully design and undertake any aspects of the evaluation, and include such activities in their TTA plan and related budget.

Translation Plan

All funded grantees are expected to prepare an intervention outcome-related manuscript for submission to a peer-reviewed journal and prepare a manuscript and/or report on the findings from the qualitative evaluation. All grantees with efficacious interventions are expected to complete packaging of the intervention. Grantees may include TTA activities, if needed, for completion of intervention packaging.

Anticipated Timeline

Component A

0-6 months

- Finalize training and technical assistance plan after consultation with CDC
- Finalize and pilot intervention materials
- Develop and submit Institutional Review Board protocols for all research activities
- Develop and submit Office of Management and Budget package for all data collection activities (as applicable)

7-48 months

- Implement the intervention, conduct quantitative and qualitative evaluation

49-60 months

- Complete all follow-up assessments
- Analyze quantitative data to assess the efficacy of the intervention
- Analyze qualitative data to inform intervention refinement/ packaging
- Finalize packaging of efficacious interventions
- Develop written reports and/or manuscripts on quantitative and qualitative intervention evaluation findings. Prepare other dissemination products, such as oral presentations and manuscripts on formative findings, baseline analyses, and lessons learned

Component B

0-18 months

- Finalize training and technical assistance plan after consultation with CDC
- Complete development, pilot, and finalize intervention materials
- Develop and submit Institutional Review Board protocols for all research activities
- Develop and submit Office of Management and Budget package for all data collection activities (as applicable)

18-48 months

- Implement the intervention, conduct quantitative and qualitative intervention

49-60 months

- Complete all follow-up assessments
- Analyze quantitative data to assess the efficacy of the intervention
- Analyze qualitative data to inform intervention refinement/ packaging
- Finalize packaging of efficacious interventions
- Develop written reports and/or manuscripts on quantitative and qualitative intervention evaluation findings for submission to CDC
- Prepare other dissemination products, such as oral presentations and manuscripts on formative findings, baseline analyses, and lessons learned

OMB/ PRA requirements are expected to apply.

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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: $10,000,000

For Component A and B grantees combined:

OAH and CDC intend to commit a combined total of approximately $10,000,000 (direct and indirect costs) for the entire five (5) year project period (09/30/2015 to 09/29/2020). Part I OAH funds will total approximately $8,000,000 (direct and indirect costs) for the entire five (5) year project period (09/30/2015 to 09/29/2020). Part II CDC funds for training and technical assistance needs will total approximately $2,000,000 (direct and indirect costs) for the entire five (5) year project period (09/30/2015 to 09/29/2020).

In 2015, OAH and CDC intend to commit a combined total of approximately $2,000,000 (direct and indirect) for the first 12-month budget period for up to three (3) awards, with at least one project evaluating an intervention targeted at young men aged 15-19 years. Two to three grantees will be awarded $666,000 to $1,000,000 (direct and indirect). Part I OAH funds will total approximately $1,600,000 (direct and indirect) for the first 12-month budget period for up to three (3) awards, with Part I funds ranging from approximately $533,000 to $800,000 per grantee. Part II CDC funds for training and technical assistance needs will total approximately $400,000 for the first 12-month budget period for up to three (3) awards, with Part II funds ranging from approximately $133,000 to $200,000 per grantee.

An applicant may request a project period of up to five (5) years. The funding amount may be up to $800,000 in Part I OAH funds and up to $200,000 in Part II CDC funds (direct and indirect) each year for the 2nd, 3rd, 4th, and 5th years of the project.

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

Applicants may request up to $800,000 in Part I OAH funds and up to $200,000 in Part II CDC funds (direct and indirect) for the first 12-month budget period**.**

If an applicant requests a funding amount greater than the ceiling of the award range for the first year ($800,000 in Part I OAH funds and $200,000 in Part II CDC funds),CDC, in collaboration with and on behalf of OAH, will consider the application non-responsive, and it will not enter into the review process. CDC, in collaboration with and on behalf of OAH, will notify the applicant that the application did not meet the submission requirements.

There is no floor (minimum amount to be awarded) for this award.

Anticipated Number of Awards: 3

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

Award Ceiling: $1,000,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Project Period Length: 5 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

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

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

If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter into the review process.

For Components A and B:

(1) Identify proposed intervention and target population to be evaluated. The proposed intervention must:

- Be targeted to young men
- Primarily focus on a selected age range between 15 and 24 years old. Interventions are not required to include all ages in this range (e.g., young men ages 20-24) and could include ages outside of this range, as long as the primary focus is between 15 and 24 years old (e.g., young men in high school)
- Not be not on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A
- Not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group)

(2) Document that the intervention developer(s) (if different from the PI) a) permits the use of the intervention for the study evaluation, and b) agrees to provide CDC and OAH with final intervention package materials.

(3) Demonstrate that the proposed intervention has, at a minimum, detailed and finalized

(**Component A**) or draft (**Component B**) logic model and implementation manual(s).

(4) Document that the principal investigator or a member of the research team has been the principal investigator or co-principal investigator on at least one study that involved a rigorous evaluation of an intervention.

Interventions listed below **will not** be accepted and the application will be considered non-responsive. Applicants **must not** propose an intervention that is:

- Already on the list of evidence-based programs as determined by the Evidence Review http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx
- Already in CDC's Compendium of Evidence-Based Risk Reduction Interventions for HIV Prevention (http://www.cdc.gov/hiv/prevention/research/compendium/rr/complete.html);
- Currently undergoing a rigorous evaluation under funding opportunity announcement OPHS/OAH-TPP PREP Tier2-2010 (http://www.hhs.gov/ash/oah/news/assets/funding_announcment_research.pdf) (See a complete list in Appendix A)

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applicants for Components A and B are required to include each of the following documents in Appendix A of the application.

(1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

(2) Applicants must provide a letter of commitment or memorandum of agreement from the developer(s) of the submitted intervention: agreeing to the use of the intervention for project activities; and agreeing to provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations.

(3) Applicants must provide a summary of the intervention, a logic model (including: the intervention goals and objectives and its theoretical basis), the age range of participants and the target population, and a summary of all intervention materials, including implementation manual(s). Applicants are encouraged to provide all intervention materials, as page limits for the Appendices permits.

(4) Applicants must provide a written acknowledgment of inclusion of both Part I and Part II activities, acknowledgment of two funding sources (Part I funds from OAH; Part II funds from CDC), and commitment to adhere to budget requirements to delineate budget and expenditures by funding source (OAH: Part I; CDC: Part II). Evidence should be provided in the form of a letter from the applicant institution and should be included in Appendix A of the application.

(5) Experience as principal investigator or co-principal investigator on at least one study that involved a rigorous evaluation of an intervention should be reflected in the Research and Related Senior/Key Person Section of the SF424 R&R for the principal investigator or a member of the research team. An abstract and reference of a report or publication for a study that involved a rigorous evaluation of an intervention should be provided in Appendix A of the application.

6. Required Registrations

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

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

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

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

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

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

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

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), 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: **02/06/2015**

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

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

Name of the Applicant
Descriptive title of proposed research

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

AMENDMENT I. New Letter of Intent Due Date: February 6, 2015

The letter of intent should be sent to:

Michael A. Brown, M.P.H.
Scientific Program Official
Extramural Research Program Office
Centers for Disease Control and Prevention
4770 Buford Hwy, NE
Mailstop F-80
Atlanta, GA 30341
Telephone: (770) 488-5118
E-mail: mab5@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

Human Subjects Section

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

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research

12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

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

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

The applicants' research plan(s) should address Part I and Part II activities that will be conducted over the entire project period and must include the following items. Unless otherwise indicated, all items are applicable to both Component A and Component B applicants.

Introduction/background

- Explain the importance of involving young men in teen pregnancy prevention efforts.
- Describe the target population(s) for proposed intervention and their risk of fathering a teen pregnancy. Include information on: rates of fathering a teen pregnancy (if available) and/or teen pregnancy or birth rates in the locality of the study; STD rates (chlamydia, gonorrhea) of young men in the proposed target population; and behavioral determinants, cultural and social norms, and/or risk behaviors in the target population.
- Describe the proposed intervention site(s), including, but not limited to social, educational, and reproductive health services provided, staffing, and the annual number of unduplicated young men in the proposed target population who currently access services.

Specific Aims

- Specify overall aims or objectives of intervention development and evaluation, training and technical assistance.

Research Strategy

- Describe how the results of the research will improve efforts to prevent teen pregnancy.
- Describe how the research findings will contribute to decreasing teen pregnancy and contribute to improvements in population health.
- Describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population.
- Describe how the proposed intervention addresses risk and protective factors for teen pregnancy that are specific to young men.

Part I: Implementation and Evaluation

Intervention:

- Describe the proposed teen pregnancy prevention intervention targeted to a specific age group of young men aged 15-24 years who are at high risk for fathering a teen pregnancy, including, but not limited to the intervention purpose, approach, structure, setting(s), content, and implementation.
- Describe the theoretical and empirical basis for the proposed intervention and how the intervention would be expected to substantially reduce the likelihood of participants fathering a teen pregnancy. Include a logic model with intervention goals and objectives that illustrates the theoretical basis of the intervention and how it will achieve the intervention's goals and objectives.
- Provide a summary of the intervention and of all intervention materials, including implementation manual(s). Applicants are encouraged to provide all intervention materials as page limits for the Appendices permit (draft materials are acceptable for Component B)
- Describe the intervention target population and review literature that supports the need for teen pregnancy prevention interventions for the specific sub-population of young males.
- Describe how the proposed intervention will be culturally appropriate, sensitive and inclusive of LGBTQ youth, and appeal to the target population.
- Describe the feasibility of implementing and scaling up the proposed intervention, including but not limited to the fit with the target setting(s) and other potential settings; length of the intervention; ease of implementation; access to eligible participants; ease of participation for the target population. If the target setting requires that males are pulled out of mixed gender groups (e.g. classes) to participate in the intervention, a strong justification for the feasibility of this approach in future implementation of the intervention must be provided. For example, providing an intervention during the school day that is only for males would <u>not</u> be feasible for most schools given that schools do not have the resources to implement separate programs for males and females.
- Describe how the target population was significantly involved in the intervention development.
- **Component A only**: Describe past implementation of the intervention, including but not limited to how long it has been implemented, the target population enrolled, the number of participants that have enrolled in the program, and in what settings the intervention has been implemented.
- **Component A only**: Describe results from previous evaluations of the proposed intervention. If available, include results from process and/or outcome evaluations. Describe whether the intervention has been rigorously evaluated (with a randomized controlled trial or other rigorous evaluation with non-randomized designs that includes an external comparison group) and whether it is currently supported by other federal funds.
- **For Component A only:** Describe plans to: form and convene a Community Advisory Board that includes members from the target population and the target setting(s); refine and finalize detailed intervention materials; and pilot test the intervention.
- **For Component B only:** Describe plans to: form and convene a community advisory board that includes members from the target population and the target setting(s); finalize intervention approaches and produce detailed intervention materials; and pilot test the intervention.

Study design:

- Describe the evaluation design, including whether the proposed study will be a randomized controlled trial or a rigorous evaluation with a non-randomized design that has an external comparison group. Applicants should provide a justification for using a non-randomized

design.

- Describe plan to reduce bias in the evaluation (e.g., through using an independent evaluator).
- Describe key outcomes to be assessed, including: 1) condom use; 2) abstinence from vaginal intercourse (primarily for teen males); 3) use of sexual and reproductive health services; 4) use of moderately or highly effective contraceptive methods, including long acting reversible contraception, by female partners; and 5) dual use of condoms and moderately or highly effective contraception. Additionally, the applicant should indicate whether the following indicators will be assessed: 1) pregnancies and births among female partners, and 2) incidence of STIs among male participants.
- Describe power analyses conducted to determine the appropriate sample size for evaluating the intervention in the target population. The study should be powered to detect change in key outcomes (e.g., condom use, abstinence from vaginal intercourse, female partners' use of moderately or highly effective contraceptive methods).
- Provide a timeline for conducting assessments at baseline and at subsequent time points during a minimum follow-up period of 24 months **(Component A)** or 12 months **(Component B).**
- Describe how study data will be analyzed using appropriate statistical methods to determine the efficacy of the intervention.

Study implementation:

- Describe plan to recruit young men into the study.
    - Describe the agencies, clinics, venues, etc., from which participants will be recruited and the anticipated number of young men who would be eligible for recruitment from each organization. Where applicable, provide letters of commitment that indicate the number of young men served by the agency, clinic, venue, etc., that would be eligible for recruitment into the study, and that the venue can be used for recruitment for the proposed evaluation. If a school is a proposed setting, provide a letter of commitment from a high-ranking school official, such as superintendent, assistant superintendent, or principal agreeing to the school(s)' participation in the research study. Demonstrate that the potential pool of eligible young men across all study sites will be large enough to successfully enroll the intended sample size (based on power calculations), accounting for expected attrition.
    - Describe prior efforts at successfully enrolling young men at risk for fathering a pregnancy or birth into trials, studies, and programs.
- Describe method of data collection, security, and data management, including issues of privacy and confidentiality.
- Describe plan to retain sample across the follow-up period.
- Describe plans for ongoing process evaluation and quality assurance throughout the project period.
- Describe what steps will be taken to ensure fidelity to the model and any observations to assess adherence to fidelity of implementation.
- Describe plan to conduct qualitative post-intervention interviews or focus groups with intervention participants and intervention staff, as appropriate, to gather feedback on the intervention and to analyze results from the interviews or focus groups.
- Demonstrate that all applicable laws, policies, procedures have been reviewed, and provide documentation confirming that the applicant has permission to collect and report data to CDC on all required performance measures from all participants.
- The applicant should describe how they will collect the performance measure data from all

participants and report it to CDC twice a year. Specific activities focused on collection and reporting of performance measure data and analyzing performance measure data for continuous quality improvement should be included in the applicant's research plan.
- The applicant should describe any potential obstacles to the collection of the performance measures and how they plan to overcome the potential obstacles.

Study dissemination:

- Describe plan to disseminate findings, including a peer-review journal article for the efficacy results.
- Describe plan to package intervention so that, if the intervention is found to be efficacious, it will be ready for immediate dissemination. The plan to package should address required elements as outlined at: http://www.hhs.gov/ash/oah/oah-initiatives/for-grantees/program-guidance/Assets/tpp_packaging_guidance.pdf

Study management:

- Describe experience and expertise of key staff and Study Team in intervention development, particularly interventions aimed at improving reproductive health outcomes among young men.
- Describe experience working with the target population within the setting(s) and site(s) where the intervention will be implemented and evaluated.
- Describe experience implementing interventions similar to the proposed intervention with the target population (e.g., clinic-based, community-level, youth development, internet-based).
- Describe experience and expertise of key staff and collaborators in conducting large scale intervention evaluations, including evaluations with a comparison group and advanced statistical methods relevant to analyzing intervention outcomes. Describe prior projects in which large samples of young men in the target population, or other groups of young men, were recruited and successfully retained in the intervention and for long-term follow-up assessments.
- Describe experience and expertise of key staff and collaborators in implementing and analyzing qualitative studies.
- Describe the Study Team's capacity to collect and report all required performance measures and to use performance measure data for continuous quality improvement.
- If applicant uses partnerships to fulfill the capacity needs for the project, such partnerships should be established in writing prior to application submission with memorandum of agreement included as an appendix. Letters should provide a detailed description of the role of each party, including acknowledgment of any planned random assignment to study conditions and its potential impact on partnering organizations (e.g., some young men within the organization may be randomly assigned not to receive the proposed intervention).
- If applicable, provide a clear roles and responsibilities for collaboration between the Study Team agencies/partners, including an organizational chart that demonstrates the relationship between all positions (including consultants, sub-grants and/or contractors). Demonstrate experience and capacity of the Study Team to successfully collaborate with one another, and/or with other similar agencies.
- Provide evidence of a clear management and staffing plan for all phases of the project.
- Provide a timeline of key activities and measureable objectives that will be used to indicate progress in each phase of the project and how measurable objectives used to indicate progress will be monitored throughout the project period.
    - Provide milestones and/or products to indicate progress in having all intervention materials finalized, an Institutional Review Board (IRB)-approved protocol, OMB

approval, and intervention sites that are ready to begin implementation within the first 6 (**Component A**) or 18 (**Component B**) months of the project.

- Describe plan to and attend a 2-3-day project launch meeting in Year 1

Part II: Training and Technical Assistance

Develop a training and technical assistance plan that includes the following

- Describe the specific capacity needs that would be met by training and technical assistance and indicate whether that need is internal to the grantee (e.g., grantee staff needs training on recruiting young men into an intervention research project) or external to the grantee (e.g., a youth-serving organization partnering with the grantee whose staff needs to be trained to implement the intervention with fidelity).
- Describe goals of the training and technical assistance to be provided.
- Specify to whom training and technical assistance will be provided.
- For consultations with other experts in the field, describe how the consultant's expertise will be used by the grantee (e.g., review of the intervention materials by other experts in interventions developed for young men) and how it will improve the intervention or the evaluation.
- Provide detailed descriptions of the specific activities that will be undertaken by the training and technical assistance providers.
- Describe plans to conduct continuous assessment of internal and external capacity needs and tailor TTA activities and TTA providers as needed.
- Describe experience and expertise of proposed internal and external TTA providers.
- Provide documentation demonstrating the expertise of those who are proposed as internal and external TTA providers.

6. Appendix

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

7. Page Limitations

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

8. Format for Attachments

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

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

9. Submission Dates & Times

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

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

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

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

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

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

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

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

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

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

Unsuccessful Submissions:

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
    b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **03/06/2015**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

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

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

Funds cannot be used for clinical services.

Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individuals/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request.

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?

- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or public health practice, and how will this improve and be of value to public health?
- If successful, does the proposed intervention have the potential to be scalable (e.g., could it be integrated into other settings that serve the target population, what resources would be needed by other settings to implement the intervention) and reach a large portion of the

population at risk?

- Are the proposed project activities likely to have a positive impact on the field of sexual and reproductive health and/or teen pregnancy in the US? If effective and scaled up after the project, what impact might the intervention have on teen pregnancy?
- To what extent will the study improve public health practice to decrease teen pregnancy?

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?

- Is there evidence of successful past collaborations with the proposed Study Team or with similar partners?
- Does the Study Team have significant experience developing and evaluating interventions aimed at improving reproductive health (e.g., contraceptive use, prevention of pregnancy, HIV, or STD) in young men in the target population?
- Are the investigators experienced at working with the target population within the target setting(s) where the intervention will be implemented and evaluated?
- Does the application demonstrate investigator capacity to recruit and retain a sample of young men in the target population large enough to meet the sample size estimates indicated by power analysis?
- Do the investigators have experience conducting large scale intervention evaluations? Does this include experience with rigorous evaluation trials (i.e., randomized controlled trials or rigorous evaluations with non-randomized designs with an external comparison group) and advanced statistical methods relevant to analyzing intervention outcomes?
- Does the study staff have experience implementing and analyzing qualitative studies?
- Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?
- Does the applicant demonstrate that the proposed training and technical assistance providers are experts in their area of focus? Will the proposed training and technical assistance activities likely enhance the capacity of the Study Team and improve the quality and rigor of the intervention and/or evaluation?

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?

- To what extent is the proposed research and intervention innovative and yet offer reasonable potential for concrete applications of interest and value to CDC and OAH?
- To what extent does the proposed intervention include novel approaches to preventing teen pregnancy when intervening with young men (e.g., intervention approach, structure, content, and/or implementation)?
- Does the applicant identify and describe influences on sexual risk or protective behaviors that have not been addressed in previous interventions?
- Does the proposed intervention address risk and protective factors for involvement in teen pregnancy that are specific to young men?

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?

- What is the extent to which the applicant's plan to carry out the activities is feasible and consistent with the stated purposes of this FOA?
- If a grantee or a partner lacks experience with any aspect of the approach, is a strategy to obtain needed training and technical assistance identified in the Part II TTA plan?

Intervention:

- To what extent did the applicant provide data justifying the need for this intervention in the target population?
- Is the proposed teen pregnancy prevention intervention targeted to and appropriate for a specific age group of young men aged 15-24 years?
- How well does the applicant describe the intervention purpose, approach, structure, setting(s), content, and implementation?
- **Component A only:** Does the applicant provide detailed, high quality intervention materials and/or a summary of all materials for the proposed intervention? Is the intervention ready for immediate implementation? How extensively has the intervention been implemented?
- **Component B only**: Does the applicant provide intervention materials and/or a summary of all materials that would provide a strong foundation for final development and implementation of the interventions? How clearly does the applicant describe how they plan to finalize intervention approaches and materials?
- How does the proposed intervention fill a significant gap in the current list of evidence-based TPP interventions as determined by the HHS Evidence Review (e.g., critical target populations and/or settings that are not served by existing interventions; see Appendix A)?
- To what extent does the applicant provide research that supports the inclusion of key determinants of risk behaviors targeted by the proposed intervention (e.g., partner communication about contraception)? Does the intervention have a strong theoretical basis for how the intervention would be expected to substantially reduce the likelihood of

participants fathering a pregnancy during their teen years and/or fathering a pregnancy to a female teen? How clearly does the logic model link program elements to intended outcomes?

- How significantly was the target population involved in the intervention development? How culturally appropriate and potentially appealing is the intervention to the target population? **Component A only:** Is there evidence from past implementation indicating that the intervention is acceptable to the target population?
- How feasible is the proposed intervention to implement during the project period and for future implementation in real-world settings?
    - How well does it fit with the existing structures in the target setting(s) and other potential settings?
    - How easy would it be to implement? Would the length or number of sessions make it challenging to retain participants in the full intervention?
    - Would it be accessible to the target population? How difficult would it be for members of the target population to participate?
    - **Component A only:** Is there evidence from past implementation indicating that the intervention is feasible to implement?
- Does the applicant describe effective steps to ensure fidelity to the model and any observations to assess fidelity of adherence to the model?
- If the target setting requires that males are pulled out of mixed gender groups (e.g. classes) to participate in the intervention, does the applicant provide a strong justification for the feasibility of this approach in future implementation of the intervention? For example, providing an intervention during the school day that is only for males would not be feasible for most schools given that schools do not have the resources to implement two separate interventions.
- **Component A only**: Do results from previous process and/or outcome evaluations of the proposed intervention provide a compelling case for rigorously evaluating the intervention?
- **Component A only**: How clearly does the applicant describe feasible plans to form and convene a community advisory board that includes members from the target population and the target setting(s); refine and finalize detailed intervention materials; recruit and train staff to deliver the intervention; and pilot test the intervention.
- **Component B only**: How clearly does the applicant describe feasible plans to form and convene a community advisory board that includes members from the target population and the target setting(s); finalize intervention approaches and produce detailed intervention materials; recruit and train staff to deliver the intervention; and pilot test the intervention.
- **Both Component A and Component B**: if any aspects of the intervention section are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

Study design:

- Does the applicant propose a strong evaluation design for either a randomized controlled trial or a non-randomized design with an external comparison group? If the applicant proposes a non-randomized design, do they provide a compelling justification?
- Does the applicant have a reasonable plan to reduce bias in the evaluation?
- Does the applicant include plans to measure key outcomes?
- Does the applicant provide power calculations demonstrating that the proposed sample size, taking into account anticipated attrition and the unit of randomization is sufficient to detect

intervention effects on main study outcomes in the target population?

- Does the evaluation design include assessments at baseline data and at subsequent time points during a minimum post-intervention follow-up period of 24 months **(Component A)** or 12 months **(Component B)?**
- Does the applicant provide an appropriate statistical approach to determine the efficacy of the intervention?
- If any aspects of the study design are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

Study implementation:

- To what extent does the applicant provide a clear and sound plan to recruit a sample of eligible young men to meet the requirements of the power calculations? Is the potential pool of eligible young men across all study sites at least twice the size of the intended sample size? How appropriate are the agencies and venues to reach the target population? Where applicable, does the applicant provide letters of commitment that indicate the number of young men served by the agency, venue, etc., that would be eligible for recruitment into the study, and that the venue can be used for recruitment for the proposed evaluation? To what extent does the applicant have prior experience successfully enrolling young men into trials, studies and/or programs?
- Does the applicant provide an adequate plan for data collection, security, and management, including issues of privacy and confidentiality?
- How strong is the applicant's plan to retain the study sample across the follow-up period?
- Does the applicant clearly describe sound plans for ongoing process evaluation and quality assurance throughout the project period, including collecting, reporting, analyzing, and using performance measure data?
- Does the applicant provide clear and sound plans to conduct and analyze data from qualitative post-intervention interviews or focus groups with intervention participants and intervention staff, as appropriate?
- If any aspects of the study implementation are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

Study management:

- Does the applicant provide a clear management and staffing plan for all phases of the project?
- Is the proposed timeline sufficiently detailed, complete, and realistic for a 5-year project period (i.e., includes key tasks for intervention development, protocol development, and conduct of the evaluation; and adequate milestones for measuring progress towards completion of these tasks)? Does the timeline include measureable objectives that will be used to indicate progress in each phase of the project and how measurable objectives used to indicate progress will be monitored throughout the project period?
- If any aspects of the study management are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

Environment

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

- Does the applicant have access to qualified personnel and partners with realistic and sufficient percentage-time commitments relative to each phase of the study timeline? Does applicant describe clear lines of authority, responsibility and supervision for all aspects of the project?
- If applicant uses partnerships to fulfill the capacity needs for the project, is there a detailed description of the roles and responsibilities of each party, including acknowledgment of any planned random assignment to study conditions and its potential impact on partnering organizations (e.g., some young men within the organization may be randomly assigned not to receive the proposed intervention)?Does the applicant provide an organizational chart that demonstrates the relationship between all positions (including consultants, sub-grants and/or contractors) on the Study Team? Does the applicant demonstrate experience and capacity of the Study Team to successfully collaborate with one another, and/or with other similar agencies?
- Does the application describe the target setting(s) and explain how the physical infrastructure, organizational infrastructure, and typical staff workload will contribute to and be affected by the implementation of the project, including the intervention itself, data collection, and evaluation?
- Do the letter(s) of commitment from the intervention site(s) delineate the roles and responsibilities of the site(s) and their staff in the project?
- If any aspects of the environment are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

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

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

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

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

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

Resource Sharing Plans

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

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Recipients will submit all de-identified study data to CDC over a secure data network

Recipient Organizations will provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for

completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

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

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

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

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

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

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

Amendment 2: As part of the scientific peer review all applications will receive a written critique. 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.

Funding preference may be used to achieve variation in funded projects based on:

- Type of setting (including, but not limited to clinics, schools, community settings, youth-serving organizations, correctional settings)
- Intervention approach (including, but not limited to: knowledge/skills/attitudes-based; youth development; social norms change)
- Target population age. The intent is to fund at least one award targeting young men within the age range of 15-19, and to fund a range of age groups.
- To prevent project and funding overlap, same (or significantly similar) projects submitted through this FOA or any of the following funding opportunities available from the HHS Office of Adolescent Health's Teen Pregnancy Prevention Program: (Capacity Building to Support Implementation of Evidence-Based TPP Programs (OAH-15-0003); Implementing

Evidence-Based Teen Pregnancy Prevention Programs to Scale in Communities with the Greatest Need (OAH-15-0004); Supporting and Enabling Early Innovation to Advance Adolescent Health and Prevent Teen Pregnancy (OAH-15-0006); Rigorous Evaluation of New or Innovative Approaches to Prevent Teen Pregnancy (OAH-15-0007)), will be funded only once.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

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

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

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

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

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

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

AR-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 Non-research

AR 32 –; FY 2012 Enacted General Provisions

ARs applicable to HIV/AIDS Awards:

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

AR-6: Patient Care

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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

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

http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_memo.html)

Federal Funding Accountability and Transparency Act of 2006

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

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the

federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http:// www.plainlanguage.gov/plLaw/index.cfm.

Tobacco and Nutrition Policies

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

Tobacco:

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

Nutrition:

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

  - http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

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

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

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

4. Cooperative Agreement Terms and Conditions of Award

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

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

activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

Collaboration, project management, and oversight

Part I:

- Providing oversight of the management and administrative aspects of the project, including maintaining an adequate staffing plan to support project activities.
- Providing oversight and management of all partnerships with other agencies and consultants that make up the full Study Team.
- Attending periodic meeting(s), as appropriate, at CDC and elsewhere to develop and finalize the research protocol, the research agenda, the data sharing agreement, publication agreement, review of analyses, and provide progress updates.
- Traveling to and attending a 2-3-day project launch meeting in Year 1 will be required.
- Participating in CDC's technical review process and complying with requests from CDC, as applicable.
- Revising the proposed evaluation design, if required. Upon funding, CDC, will review the proposed evaluation design (updated in response to comments during the grant review process) to ensure the design is in a strong position to meet the HHS evidence standards. Revision may be required if the design is not adequate.
- Complying with ongoing monitoring and reporting to CDC on the status of each evaluation.
- Meeting all evaluation-related reporting requirements. These requirements, subject to change over the course of the grant, are in addition to the requirements for performance measures reporting, including, but not limited to: baseline equivalence analysis and updated CONSORT diagram(s).
- Participating in monthly phone calls that will include CDC staff and may include OAH staff
- Attending twice yearly webinars on required evaluation reporting.
- When feasible, shared measures will be used across grantees funded under this FOA

Part II:

- Identifying TTA needs, and developing a TTA plan tailored to meet grantee and/or grantee partners' needs for training and technical assistance to ensure high-quality implementation and rigorous evaluation of the intervention; revising TTA plan as needed as new TTA needs are identified.
- Providing oversight and management of all TTA activities, including subcontracts with technical assistance providers (if used).

Preparing the proposed intervention for a rigorous evaluation
Part I:

- Convening a community advisory board
- Refining (Component A) or finalizing development (Component B) of intervention materials and producing detailed intervention materials
- Recruiting and training staff to deliver the intervention
- Pilot testing the intervention
- Obtaining all necessary permissions and/or clearances for the intervention materials (prior to

submitting an application, and any others needed during the project)
- Submitting all intervention materials to CDC and OAH for the medical accuracy review and verifying that all required modifications have been made and accepted by CDC and OAH prior to use in the grant.

Part II:

- Ensuring any TTA needs related to the above preparation activities are met (for grantee or any partners) as specified in the TTA plan.

Implementing the efficacy and qualitative studies

Part I:

- Completing training and participating in technical assistance from CDC, as applicable, on developing and implementing research protocols that meet HHS evidence standards.
- Developing research study materials and protocols, including, but not limited to:
    - Culturally sensitive quantitative measures of immediate and primary outcomes
    - Qualitative interview guide(s)
    - Sampling and recruitment strategies to enroll adequate numbers of the proposed target population
    - Appropriate referral mechanisms to local resources that provide services to participants (e.g., mental health counseling, financial services, substance abuse treatment, and other services).
    - All materials required for IRB submission for local and CDC IRB review (e.g., protocol, consent forms, data collection materials, recruitment materials). The protocols must be designed to adequately describe implementation and evaluation of the proposed intervention and meet HHS regulations 45 CFR 46.
- Developing package for review by the Office of Management and Budget, under the Paperwork Reduction Act, including data collection instruments (as applicable)
- Obtaining, and maintaining all local Institutional Review Board approvals for the Study Team
- Developing and implementing stringent safeguards and procedures for protecting the rights and confidentiality of all research participants.
- Developing manuals of operations and implementing all study activities, including but not limited to:
    - 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.
    - Implementing the intervention, within the context of the evaluation/research study.
    - Collecting all study data, including any laboratory tests that may be proposed.
    - Ensuring data entry, security, and quality/accuracy.
    - Submitting in a timely manner de-identified data to CDC over a secure data network.
    - Collecting, reporting, analyzing, and using performance measure data and submitting it to CDC twice a year.

Part II:

- Ensuring TTA needs related to implementation of the efficacy and qualitative studies are met as noted in the TTA plan

Data analyses

Part I

- Using appropriate statistical techniques to analyze the data needed to evaluate the intervention.
- Using appropriate qualitative data analysis techniques to support intervention packaging, dissemination, and implementation.
- Develop a data sharing plan.
- Work collaboratively with CDC staff on the design, analyses, and dissemination of study results, including sharing de-identified data with CDC for secondary analyses.
- Including any data analysis training and technical assistance needs (for grantee or any partner/s in the Part II TTA plan.

Part II:

- Ensuring any data analysis TTA needs (for grantee or any partners) are met as specified in the TTA plan.

Dissemination

Part I:

- Finalizing packaging of efficacious interventions per CDC and OAH required elements as outlined at: http://www.hhs.gov/ash/oah/oah-initiatives/for-grantees/program-guidance/Assets/tpp_packaging_guidance.pdf
- Submitting written report and/or manuscript reporting post-intervention findings to CDC
- Submitting manuscript reporting efficacy findings to CDC clearance and peer-review journal
- Developing a publication agreement
- Including acknowledgment on the funding source on all documents funded under this announcement, including but not limited to intervention materials and publications*: This publication was made possible by Grant/Cooperative Agreement Number_ [to be determined] from the Centers for Disease Control and Prevention (CDC) through a partnership with the U.S. Department of Health and Human Services' (HHS) Office of Adolescent Health. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC or HHS.*

Part II:

- Ensuring any dissemination and packaging TTA needs are met as specified in TTA plan.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS, HHS/PHS, and applicable HHS/CDC policies. However, the Recipient Organization will provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations.

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards.

An agency program official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the Notice of Award.

There are two separate CDC scientific roles – Scientific Collaborator (SC) and the Scientific Program Official (SPO).

In this cooperative agreement, a NCCDPHP SC is a partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination.

The SC will:

- Work cooperatively in the development and/or refinement of the intervention and the design of the research protocols. This includes providing training and technical assistance from CDC, as applicable, on developing and implementing research protocols that meet HHS evidence standards and reviewing grantees' TTA plan.
- Provide technical assistance, as needed, for intervention and research implementation.
- Work cooperatively to conduct literature reviews and analyses of existing data sets to help ensure that the intervention protocol addresses empirically verified correlates of high-risk sexual behaviors within the current study populations.
- Assist in the development of a research protocol for IRB review by the institutions collaborating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
- Develop package for review by the Office of Management and Budget, under the Paperwork Reduction Act, including data collection instruments (as applicable).
- Conduct ongoing program monitoring of grantee intervention development and refinement, implementation, research, and TTA activities.
- Monitor and evaluate scientific and operational accomplishments of this project through frequent telephone contact, 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.

The SPO will:

- Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Additionally, an HHS/CDC NCCDPHP project officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of this project.

Areas of Joint Responsibility include:

- Participating in periodic conference calls and meetings
- Participate in regular PI calls
- Sharing data and collaborating with other investigators to answer common research questions, if appropriate
- Developing common outcome measures, if appropriate

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.

Additional information for 3. Final Reports

Public Health Relevance and Imact: This section should include an impact evaluation report. The impact evaluation report will provide the evidence from the intervention evaluation in a consistent, comprehensive format. The report will include a description of the intervention and any programming received by control group participants, study design, study findings, and conclusions. It is expected that all evaluation reports will be published on the OAH website. CDC will submit the report to the HHS Evidence Review.

Annual reports are required and should include the same information as requested for the Yearly Non-Competing Grant Progress Report (PHS 2590), excluding the New Budget Period Budget, as described below in B. Content of Reports, and is due 90 days after the end of the budget period.

4. Annual progress report

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

    a. Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

    b. Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research to policy or 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 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 policy or practice?
- How will the project improve or effect the translation of research findings into policy or practice?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- 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, 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.
- Performance measures: Must collect and report all required performance measures. See Appendix B for example performance measures on which the performance measures for this project will be based.

A. Submission of Reports

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

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

B. Content of Reports

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

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

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

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

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

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

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

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

    - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
    - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

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

2. Annual Federal Financial Reporting

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

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

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls

within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

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

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

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

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

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

Scientific/Research Contact(s)
Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Office

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

Peer Review Contact(s)

Chris Langub, Ph.D.

Scientific Review Official

Extramural Research Program Office

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-3584

E-mail: ee06@cdc.gov

Financial/Grants Management Contact(s)

LaKasa Wyatt

Procurement and Grants Office, Grants Office, Branch III

2920 Brandywine Road, Mailstop E-09

Atlanta, GA 30341

Telephone: 770 488-2728

Email: lgw5@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

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

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

This program is authorized under Division H, Title II of the Consolidated Appropriations Act, 2014 (Public Law No. 113-76), and the Continuing Resolution thus far for FY 2015 (Public Law No. 113-164), and Section 317K and 301(a) of the Public Health Service Act, 42 U.S.C. 247b-12, 241(a).

APPENDIX A - Interventions Already Reviewed or Undergoing Review

Interventions listed in this appendix are not acceptable for this funding announcement.

1. List of Evidence-based Programs as Determined by the HHS Teen Pregnancy Prevention Evidence Review http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx

Aban Aya Youth Project

Adult Identity Mentoring (Project AIM)

All4You!

Assisting in Rehabilitating Kids (ARK)

Be Proud! Be Responsible!

Be Proud! Be Responsible! Be Protective!

Becoming a Responsible Teen (BART)

Children's Aid Society (CAS) -- Carrera Programs

¡;Cuídate!

Draw the Line/Respect the Line

Families Talking Together (FTT)

FOCUS

Health Improvement Projects for Teens (HIP Teens)

Heritage Keepers Abstinence Education

HORIZONS

It's Your Game: Keep it Real (IYG)

Making a Difference!

Making Proud Choices!

Project IMAGE

Project TALC

Promoting Health Among Teens! Abstinence-Only Intervention

Promoting Health Among Teens! Comprehensive Abstinence and Safer Sex Intervention

Raising Healthy Children (formerly known as the Seattle Social Development Project)

Reducing the Risk

Respeto/Proteger

Rikers Health Advocacy Program (RHAP)

Safer Choices

Safer Sex

SiHLE

Sexual Health and Adolescent Risk Prevention (SHARP) (formerly known as HIV Risk Reduction Among Detained Adolescents)

Sisters Saving Sisters

STRIVE

Teen Health Project

Teen Outreach Program (TOP)

17 Days (formerly What Could You Do?)

2. Complete Listing of Risk Reduction Evidence-based Behavioral Interventionshttp://www.cdc.gov/hiv/prevention/research/compendium/rr/complete.html

AMIGASAssisting in Rehabilitating Kids (ARK) Becoming a Responsible Teen (BART) Be Proud! Be Responsible! Brief Alcohol Intervention for Needle Exchangers (BRAINE) Brief Group Counseling Centering Pregnancy Plus (CPP) CHAT Choices

Choosing Life: Empowerment, Actions, Results (CLEAR) Cognitive Behavioral STD/HIV Risk-Reduction Communal Effectance-AIDS Prevention (CE-AP)Community Promise Condom Promotion Connect: Couple Connect: Woman Alone Connect 2 ;

¡;Cuídate! Doing Something Different Drug Users Intervention Trial (DUIT)

Eban

EXPLORE

Familias Unidas

Female and Culturally Specific NegotiationFemale Condom Skills Training Project FIO (The Future Is Ours)Focus on the Future Focus on Youth FOY + ImPACT Health Improvement Project (HIP)Healthy Living Project (HLP) ; Healthy LoveHealthy Relationships HIV Education and Testing HoMBReS HORIZONS Project IMAGE In The Mix Insights Intensive AIDS Education LIFT “;light”; Many Men, Many Voices (3MV) Modelo de Intervención Psicomédica (MIP)Mpowerment Motivational Interviewing -based HIV Risk Reduction Nia Options/Opciones Project Preventing AIDS through Live Movement and Sound (PALMS) ; Partnership for Health (Loss-Frame) Personalized Cognitive Risk-Reduction Counseling POLPositive Choice: Interactive Video Doctor Real AIDS Prevention Project (RAPP)REAL MenReal Men Are Safe (REMAS) RESPECT: Brief CounselingRESPECT: Enhanced Counseling RESPECT: Brief Counseling + Booster SAFE (Standard Version)Safe in the City Safe on the OutsSafer Sex Safer Sex Skills Building (SSSB)SafeTalk Safety Counts Self-Help in Eliminating Life-Threatening Diseases (SHIELD)SEPA Seropositive Urban Men’;s Intervention Trial (SUMIT)Sistering, Informing, Healing, Living, and Empowering (SiHLE)Sisters Saving Sisters Sister-to-Sister: Group Skills-building Sister-to-Sister: One-on-one Skills-building Sniffer START Street Smart STRIVE Teen Health ProjectTogether Learning Choices (TLC) Treatment Advocacy Program (TAP) ;

Video Opportunities for Innovative Condom Education and Safer Sex (VOICES/VOCES) Women Involved in Life Learning from Other Women (WiLLOW)

Women’;s Co-Op

Women's Health Promotion (WHP)

3. List of Programs Currently Being Evaluated Under OPHS/OAH-TPP PREP Tier2-2010

Alaska Promoting Health Among Teens, Comprehensive Abstinence and Safer Sex Project (AKPHATComp)

Ateyapi Identity Mentoring (AIM) Program

Be yoU, Talented, Informed, Fearless, Uncompromised, and Loved (BUtiful) (an electronic translation of the intervention SiHLE)

Be Yourself/Sé Tu Mismo

Crossroads

Demoiselle 2 Femme

Development for Youth

FatherWorks

Gender Matters (GEN.M)

Go Grrrls

Haitian American Responsible Teens (HART)

Healthy Futures

More than a Dream/Más que un sueño

Need to Know (N2K)

Plain Talk Philadephia

Planned Potential

Positive Prevention PLUS: Sexual Health Education for California Youth

POWER Through Choices 2010

Prevent Second Pregnancy Project

Teen Options to Prevent Pregnancy (TOPP)

Teen Outreach Program (TOP) Plus Text Message Enhancement (TOP®4ME)

Teen Parent Project

Teen PEP

The Lighthouse Project

The Web of Life

WAIT Training

4. Summary of Study Quality Criteria (for a full description, see: http://tppevidencereview.aspe.hhs.gov/pdfs/Review%20protocol%20v3.pdf)*

Criteria Category	High Study Rating	Moderate Study Rating	Low Study Rating
1. Study design	Random or functionally random assignment	Quasi-experimental design with a comparison group; random assignment design with high attrition or reassignment	Does not meet criteria for high or moderate rating
2. Attrition	What Works Clearinghouse standards for overall and differential attrition	No requirement	Does not meet criteria for high or moderate rating
3. Baseline equivalence	Must control for statistically significant baseline differences	Must establish baseline equivalence of research groups and control for baseline outcome measures	Does not meet criteria for high or moderate rating
4. Reassignment	Analysis must be based on original assignment to research groups	No requirement	Does not meet criteria for high or moderate rating
5. Confounding factors	Must have at least two subjects or groups in each research group and no systematic differences in data collection methods	Must have at least two subjects or groups in each research group and no systematic differences in data collection methods	Does not meet criteria for high or moderate rating

*Although the criteria state that a majority of study participants must be <19 years old, for this funding announcement, evaluation designs with older male populations (>19 years old) will be accepted.

APPENDIX B: TPP Performance Measures for Tier 1 C/D and Tier 2 Grantees

September 2014

ALL GRANTEES

Participant ID (unique and non-identifiable, i.e. no names or birthdates)

Demographic characteristics (collected and entered for every participant individually)

- Age
- Grade
- Gender
- Race
- Ethnicity
- Language spoken at home
- Special populations (if applicable)

Fidelity (based on facilitator and observer logs, observer quality rating & fidelity process form)

- In the past program year, what percentage of sessions were observed by an independent observer for fidelity assessment?
- What is the median percentage of activities completed, across sessions observed?
    - Minimum
    - Maximum
- What is the minimum and maximum percentage of activities completed, across sessions observed?
- What percentage of sessions were rated either 4 or 5 for overall quality?
- For what percentage of sessions completed do you have a completed fidelity monitoring log from the facilitator?
- What is the median percentage of activities completed, across sessions for which you have a completed fidelity monitoring log?
- Across cohorts, what is the median percentage of sessions implemented?
- What is your score on the 24-point fidelity process scale?

Dosage of services received by participants (attendance is entered for every program participant for every scheduled class/session). OAH calculates the following:

- What is the median % of program services received by youth?
- What is the median % of program services received by parents (if applicable)?
- What % of youth received at least 75% of the program?
- What % of parents received at least 75% of the program?

Partners

Formal partners are organizations (e.g., schools) with whom the grantee has an MOU, contract or other formal written agreement in place to provide service or other contribution relevant to the TPP

program.

Informal partners are organizations with whom the grantee does not have a formal written agreement in place.

- How many formal/informal partners are you currently working with?
- How many of these formal/informal partners are new for this reporting period?
- How many formal/informal partners did you lose during this reporting period?
- What is the total number of formal/informal partners you have had since the beginning of the project?
- How many formal/informal partners have you lost since the beginning of the project?

Training

- In the reporting period, how many *new* intervention facilitators (including teachers) have you or one of your partners trained? Please include only training provided to new facilitators.
- In the reporting period, how many intervention facilitators (including teachers) have you or one of your partners given follow-up training?

Dissemination

- How many manuscripts have you had accepted for publication in the past year (including both articles that were published and those that have been accepted but not yet published)? Do not include manuscripts previously reported as published.
- Please list the references for any published manuscripts published in the past year.
- How many presentations have you made at each of the following levels in the past year:
    - National or regional? ____Please list titles of all presentations and venue (e.g., conference or organization to which the presentation was made)
    - State? ____Please list titles of all presentations and venue (e.g., conference or organization to which the presentation was made)

Outcome measures

- Ever had sex
- Ever been pregnant/gotten someone pregnant
- # of times been pregnant/gotten someone pregnant
- Any sex in past 3 months
- # of times had sex in past 3 months
- Had sex without a condom in past 3 months
- # of times had sex without a condom in past 3 months
- Had sex without birth control in past 3 months
- # of times had sex without birth control in past 3 months
- Intent to have sex in next year
- Intent to use a condom in next year
- Intent to use birth control in next year
- Use of sexual or reproductive health services

Actual Participant-Level Performance Measure Questions

Date _____/_____/_____

Demographic Questions (Inform Reach)

1. In what month and year were you born?

MARK (X) ONE Month and One Year

ð	January	ð 2002
ð	February	ð 2001
ð	March	ð 2000
ð	April	ð 1999
ð	May	ð 1998
ð	June	ð 1997
ð	July	ð 1996
ð	August	ð 1995
ð	September	ð 1994
ð	October	ð 1993
ð	November	ð 1992
ð	December	ð 1991

Alternative question: How old are you? _____

2. What grade are you in? (If you are currently on vacation between grades, please indicate the grade you will be in when you go back to school).

MARK (X) ONE ANSWER

- ð 6_{th}
- ð 7_{th}
- ð 8_{th}
- ð 9_{th}
- ð 10_{th}
- ð 11_{th}
- ð 12_{th}
- ð Ungraded
- ð College/Technical school
- ð Not currently in school

3. Are you male or female?

MARK (X) ONE ANSWER

- ð Male
- ð Female

4. Are you Hispanic or Latino?

MARK (X) ONE ANSWER

- ð Yes

ð No

5. What is your race?

MARK (X) one or MORE THAN ONE ANSWER

ð American Indian or Alaska Native

ð Asian

ð Black or African-American

ð Native Hawaiian or Other Pacific Islander

ð White

When you are at home or with your family, what language or languages do you usually speak?

MARK (X) one or MORE THAN ONE ANSWER

ð English

ð Spanish

ð Chinese language such as Mandarin or Cantonese

ð Some other language: _____

Indicate Special Populations (as applicable)

- Pregnant or parenting teens
- Youth in foster care
- Homeless youth
- Youth in the juvenile justice system
- Other

Participant-Level Questions (Rigorous evaluations only)

The (next/first) questions are about sexual intercourse. By sexual intercourse, we mean a male putting his penis into a female's vagina.

1. Have you ever had sexual intercourse?

ð Yes

ð No à Skip to ***Question 6***

2. To the bestof your knowledge, have you ever been pregnant or gotten someone pregnant, even if no child was born?

ð Yes

ð No –> Skip to ***Question 3***

2a. To the best of your knowledge, how many times have you been pregnant or gotten someone pregnant?

_____

3. Now please think about the past 3 months. In the past 3 months, have you had sexual intercourse, even once?

ð Yes

ð No à Skip to ***Question 6***

3a. In the past 3 months, how many times have you had sexual intercourse?

_____

4. In the past 3 months, have you had sexual intercourse without you or your partner using a condom?

ð Yes

ð No à Skip to ***Question 5***

4a. In the past 3 months, how many times have you had sexual intercourse without using a condom?

_____

5. In the past 3 months, have you had sexual intercourse without you or your partner using any of these methods of birth control?

- Condoms
- Birth control pills
- The shot (Depo Provera)
- The patch
- The ring (NuvaRing)
- IUD (Mirena or Paragard)
- Implant (Implanon)

ð Yes

ð No à Skip to ***Question 6***

5a. In the past 3 months, how many times have you had sexual intercourse without using any of these methods of birth control?

_____

6. Do you intend to have sexual intercourse in the next year, if you have the chance?

ð Yes, definitely

ð Yes, probably

ð No, probably not

ð No, definitely not

7. If you were to have sexual intercourse in the next year, do you intend to use (or have your partner use) a condom?

ð Yes, definitely

ð Yes, probably

ð No, probably not

ð No, definitely not

8. If you were to have sexual intercourse in the next year, do you intend to use (or have your partner use) any of these methods of birth control?

- Condoms
- Birth control pills
- The shot (Depo Provera)

- The patch
- The ring (NuvaRing)
- IUD (Mirena or Paragard)
- Implants (Implanon)

ð Yes, definitely

ð Yes, probably

ð No, probably not

ð No, definitely not

APPENDIX C

Q&As RFA-DP-15-007

Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males

Question 1: Are you able to say when the FOA is likely to come out?

Answer: Thank you for your interest in RFA-DP-15-007 *Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males*. This FOA was published on Grants.gov December 23, 2014. The FOA is available at the following website.

http://www.grants.gov/web/grants/search-grants.html?keywords=RFA-DP-15-007

Question 2: The amount of available funding per site and the length of the project?

Answer: Thank you for your interest in RFA-DP-15-007, *Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males*.We anticipate funding 2-3 grantees, for the 5-year project period. Funding per grantee will depend on the number of awards. For the first year (and each subsequent year), applicants will have a total of $666,000 to $1 million dollars. This total must be split between Part I and Part II activities – $533,000-$800,000 for Part I and $133,000-200,000 for Part II. If an applicant requests a funding amount greater than the ceiling of the award range for the first year ($800,000 in Part I OAH funds and $200,000 in Part II CDC funds), CDC, in collaboration with and on behalf of OAH, will consider the application non-responsive, and it will not enter into the review process.

Please see the table below for additional funding information.

	Funder	Activities	Estimated Total Year 1 Funding (2-3 grantees)	Year 1 Funding Range	Year 1 Budget Ceiling	Annual Estimated Funding Years 2-5	Total Estimated Funding for the 5-Year Project Period
Part I	OAH*	Implementation and Evaluation	1.6 m	533k-800k	800k	533k-800k	~2.6m-4m

Part II	CDC	Training and Technical Assistance	400k	133k-200k	200k	133k-200k	~666k-1m
Total			2 m	666k-1m	1m	666k-1m	~3.3m-5m

OAH* – HHS Office of Adolescent Health

Question 3: I was unable to locate the full application for RFA-DP-15-007. Could you please advise on how to get it?

Answer: Thank you for your interest in RFA-DP-15-007, *Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males.* The FOA is available at the following website http://www.grants.gov/web/grants/view-opportunity.html?oppId=270804&;CFID=3551476&;CFTOKEN=62d4a5459995ed60-F3B1A6D2-944B-28C0-403CD848EBF31233&;jsessionid=08E250944701455333147C2E12AE5941.PROD_1

and below is a list of contacts for this funding opportunity.

Application Submission Contacts

1. For questions regarding **Grants.gov** registration and submission, downloading or navigating forms please contact the below support center.

Grants.govCustomerSupport

Contact Center Phone: 800-518-4726

Email: support@grants.gov

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

2. For questions regarding **eRA Commons** registration, tracking application status, post submission issues, FFR submission please contact the eRACommonsHelpDesk.

Telephone: 301-402-7469 or 866-504-9552 (Toll Free) or TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7:00 am – 8:00 pm, U.S. Eastern Time

3. For technical information please contact the CDC Technical Information Management Section (TIMS), Procurement and Grants Office

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7:00 am – 4:30 pm, U.S. Eastern Standard Time PGO approved 1-3 previously.

Question 4: Do you think it will still have the same due date of 2/20?

Answer: Amendment 1 posted 1.22.15 http://www.grants.gov/web/grants/view-opportunity.html?oppId=270804&;CFID=3551476&;CFTOKEN=62d4a5459995ed60-F3B1A6D2-944B-28C0-403CD848EBF31233&;jsessionid=08E250944701455333147C2E12AE5941.PROD_1

The due date for the FOA was extended to March 6, 2015.

Question 5: Also how finalized does the intervention need to be or can we use the first year to modify and finalize? We have been doing family planning in our clinics for a long time but haven't specifically focused on males (do work with males).

Answer: As noted in the FOA on page 6 in the Background and Purpose section: Component B: Applicants for Component B will have a partially developed intervention to be completed prior to the evaluation. To be considered partially developed, applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

Question 6: I have a found a couple interventions (e.g., Wise Guys) that may meet the criteria or we can take our approach (health educator and tailoring) and augment it with evidence-based components/structure. What we are really interested in doing is figuring out how to implement the intervention through mobile health technology specifically or texting– which would be an innovative venue and potentially more sustainable.

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted in the FOA Section I under the "Background and Purpose" header, Component B of the FOA allows for applicants to have a partially developed intervention to be completed prior to the evaluation. Successful applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention

target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 7: Can we look to using the Flash curriculum or Wise Guys – both have or have had some evaluation but aren't on the lists. If there is any randomized evaluation does that exclude us from using or drawing upon them?

Answer: We can not comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 8: Regarding existing interventions, is it allowable to use and intervention that was designed for both men and women in the target age group?

Answer: This type of application would likely fall under Component B, because it was originally designed for females and males and would need to be designed for young men, specifically. As noted in the FOA in the Special Eligibility Requirements section: The proposed intervention must be targeted to young men. The intent of the FOA is to evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. As noted in the Research Plan Component, Applicants should describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population. Applicants should describe how the proposed intervention addresses risk and protective factors for teen pregnancy that

are specific to young men.

As noted in the FOA in the Background and Purpose section, successful Component B applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials.

As noted under the Special Eligibility Requirements, the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A.

Question 9: Are we correct in assuming that some appreciable part of the intervention can live online?

Answer: There are no criteria in the FOA that would preclude the intervention from being online.In the FOA; Section IV. Application and Submission Information; Part I: Implementation and Evaluation; Study Dissemination the FOA states: Describe plan to package intervention so that, if the intervention is found to be efficacious, it will be ready for immediate dissemination. The plan to package should address required elements as outlined at: http://www.hhs.gov/ash/oah/oah-initiatives/for-grantees/program-guidance/Assets/tpp_packaging_guidance.pdf , Please Note: Do not include hyperlinks in any part of your submission, as they do not show when the application is uploaded into Grants.gov.

Question 10: We would like to better understand what is meant by, "Interventions should target young men at high risk of fathering a teen pregnancy...." Does this allow for the inclusion of mixed gender interventions that include young men at high risk? In other words, if the application can demonstrate that this approach is intentional will it be considered?

Answer: We cannot comment on specific topics or approaches. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

In the FOA, Section III Eligibility Information; 3. Special Eligibility Requirements the FOA states the proposed intervention must be targeted to young men. The target population refers to the intervention participants.

Question 11: Although the projects will be funded in September 2015, do you have a general sense of, after gaining approval for intervention content, when evaluation implementation might occur? (We are interested in the Component A proposal type.)

Answer: In the FOA under Translation Plan, Anticipated Timeline; the FOA states:

- Component A; 0-6 months; Complete development, pilot, and finalize intervention materials.

Question 12: Can you provide me with the correct version of the required proposal structure. The FOA seems to reference three versions:

- Part 2, Section I; Full Text, Funding Opportunity Description (Pages 4-13)—Essentially provides somewhat of a format;
- Part 2, Section IV; Application and Submission Information; Number 5-PHS 398 Research Plan Component (Page 22-23). The third one is embedded in the second bullet point.

Answer: Please refer to the SF424(R&R) for application instructions and forms. Section I of the FOA describes the purpose and intent of the FOA and outlines the research objectives. Section IV,

#5 PHS 398 Research Plan Component of the FOA depicts the sections of the PHS 398 research plan that applicants should address as part of their application. Also in Section IV, following the 398 Research Plan Components, the FOA provides detailed guidance on what should be addressed in an application. Typically, the detailed information is included in the Research Strategy section of the application.

Question 13: On p. 22 of the FOA, in the list of 16 parts of the HHS 398 the FOA indicates that, as is usually the case, the Introduction section is omitted in a new application. However, on p. 23 the FOA seems to indicate that the introduction should be included in ALL applications, since I cannot conceive of writing an responsive application that does not include the info listed under information/background on p. 23. If, as is usual, the introduction is omitted in a new application, then where should this info go?

Answer: In the FOA Section IV. Application and Submission Information, #5 PHS 398 Research Plan Component, the 16 sections of the PHS 398 are outlined. Section 1. Introduction to Application is for Resubmissions and Revisions—this section should not be included in your New application. In the FOA, following the PHS 398 Component listing, is a detailed section providing guidance on what should be addressed in an application. This guidance includes a heading "Introduction/background"; information addressing "Introduction/background" should be included in the application, but it is at the discretion of the PI to determine location in the application. The similarity in language in these two sections may have led to this potential confusion. Please note: all applicants are encouraged to refer to the SF424(R&R) application guidance for more information.

Question 14: On p.8 of the RFA where it states the intervention cannot be one that has been adapted from an evidence-based intervention for HIV: Can the intervention be one that has been adapted from an Evidence-based intervention listed for HIV prevention, but has gone through an entirely different efficacy trial designed to include an age group (15-17) that was not previously included (18-29) with expanded objectives and is not currently considered an EBI?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted in the FOA Section I under the "Background and Purpose" header, Component B of the FOA allows for applicants to have a partially developed intervention to be completed prior to the evaluation. Successful applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention

must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 15: We got hung up on the last sentence of the 2nd to last para on p.8; "or those that replicate or make changes (adaptations) to these interventions (See a complete list in FOA Appendix A)", though the intervention in question is not one of the EBIs listed, there were some adaptations involved from one of the EBIs listed.

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question16: We are looking at a male empowerment program that has been elevated in the president's My Brother's Keeper initiative as a key program. It has been evaluated to be effective in having non-pregnancy prevention outcomes. There is another major evaluation underway. We are exploring an adaptation that would include teen pregnancy topics, and we would like to propose this adaptation under component B to evaluate the effectiveness of preventing teen pregnancy. Would this intervention be eligible since it has already been rigorously evaluated but not for pregnancy prevention outcomes? On the call they said yes, but I want to make sure before we go through the

process to apply.

Answer: Under Component B, there is nothing in the FOA that precludes applicants from proposing an intervention that is adapted from an intervention that has been rigorously evaluated, as long as the original intervention is not in the list under Appendix A.

As noted in the FOA Section I under the "Background and Purpose" header, Component B of the FOA allows for applicants to have a partially developed intervention to be completed prior to the evaluation. Successful applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 17: Do I understand the ownership position correctly? (Organization retains rights, Federal government receives finished copies and can distribute without limitation).

Answer: In section VI under the cooperative agreement terms and conditions of award (FOA Number: RFA-DP-15-007), the Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS, HHS/PHS, and applicable HHS/CDC policies. However, the Recipient Organization will provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations. CDC and OAH do not intend to sell or directly market any program developed under this award, CDC and OAH reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work developed under this award for Federal purposes and to authorize others to do so (45 CFR §§ 75.322-Copyrights).

CDC and OAH would like to showcase final program packages and evaluation results on their websites. The method of posting the final program package on their websites would be read-only. Persons interested in learning more about the program or in obtaining materials or training would be directed to the appropriate contact (e.g., developer, publisher, supplier, etc.)

Question 18: Does the organization retain exclusive rights to provide training and TA to those who access the curriculum through the Federal government?

Answer: CDC and OAH would like to showcase final program packages and evaluation results on

their websites. The method of posting the final program package on their websites would be read-only. Persons interested in learning more about the program or in obtaining materials or training would be directed to the appropriate contact (e.g., developer, publisher, supplier, etc.).

Question 19: Will the Federal government be willing to enter into an MOA with the organization to assure exclusive rights to T&TA?

Answer: CDC and OAH do not intend to sell or directly market any program developed under this award, but do reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work developed under this award for Federal purposes and to authorize others to do so (45 CFR §§ 75.32-Copyrights).

CDC and OAH would like to showcase final program packages and evaluation results on their websites. The method of posting the final program package on their websites would be read-only. Persons interested in learning more about the program or in obtaining materials or training would be directed to the appropriate contact (e.g., developer, publisher, supplier, etc.).

Question 20: An eligible intervention under Component A is one that "has not been rigorously evaluated (I.e. Randomized controlled trial or non-randomized design with external comparison group)." Is there a definition for "rigorously evaluated"? I assume just because an RCT or QED study has been done on an intervention, regardless of the quality of the study, that this does not qualify the intervention as having been "rigorously evaluated". The OAH FOA AH-TP2-15-002 (page 4) states, "For this FOA, rigorous evaluation is defined as high quality randomized controlled trials (RCTs), quasi-experimental designs (QEDs), or Regression Discontinuity Designs (RDD) designed and implemented to meet the standards for a high or moderate rating on the HHS TPP Evidence Review." Would this definition of "rigorous evaluation" hold for the CDC RFA-DP-15-007 as well?

Answer: The intent of the FOA is to evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. The applicant must demonstrate how their research topic fits within the intent of the FOA. The FOA utilizes the terminology "rigorous evaluation" throughout the document. In Section III "Responsiveness", the term is further described as "rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group)."

If applicants propose an intervention that has been evaluated with a randomized-control trial or non-randomized design with external comparison group, applicants must clearly demonstrate that the proposed intervention has not been rigorously evaluated. This information must be provided in Appendix A of the application.

Question 21: Does the existing intervention have to have been originally designed only for males, or can we adapt a co-ed intervention to be tailored for males (under Component B)?

Answer: We cannot comment on specific topics or approaches. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

This type of application would likely fall under Component B, because it was originally designed for females and males and would need to be designed for young men, specifically. As noted in the FOA on page 18 of the Special Eligibility Requirements: The proposed intervention must be targeted to

young men. The intent of the FOA is to evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. As noted on page 23 of this FOA of the Research Plan Component, Applicants should describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population. Applicants should describe how the proposed intervention addresses risk and protective factors for teen pregnancy that are specific to young men.

As noted in the FOA on page 6 in the Background and Purpose section, successful Component B applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials.

As noted on page 18 of the FOA, under the Special Eligibility Requirements, the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and has not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 22: Could we develop a version for females along with the version for males, so that colleges could offer an intervention to students of both genders, even though the evaluation would only cover the males?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. There are no restrictions in the FOA barring grantees from developing a second intervention, although project funds can only be used for activities specifically addressing the intent of this FOA. The intent of the FOA is to rigorously evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. And as noted on page 23 of this FOA of the Research Plan Component, applicants should describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population. Applicants should describe how the proposed intervention addresses risk and protective factors for teen pregnancy that are specific to young men. As noted in the FOA on page 6 in the Background and Purpose section, successful Component B applicants will have conducted formative research and/or consulted with members of the target population.

Question 23: When serving males 18 – 24, it is quite likely that some will have partners who are not teens. Since focus is pregnancies among teens, is it acceptable for some of the male participants to have partners who are adults? We see it as being very difficult to control or limit this.

Answer: There are no specifications in the FOA regarding the age of the participants' female partners for intervention outcomes or intervention target population. As noted under the Approach

section:

The proposed intervention should be targeted to young men within the age range of 15-24 years who are at high risk for fathering a teen pregnancy.

The primary outcomes to be assessed are increased: condom use; abstinence from vaginal intercourse (primarily for teen males); use of sexual and reproductive health services; female partners' use of moderately effective contraception (hormonal injection; patch; ring; pill) or highly effective long-acting reversible contraception (implant; IUD); and dual use of condoms and moderately or highly effective contraception. The applicant should address possible limitations in assessing outcomes related to female-controlled methods of contraception (i.e., moderately or highly effective contraceptive methods), since these methods are not under the direct control of the male intervention participants. Measures will need to be designed to maximize reliability.

Question 24: P. 10, 2nd paragraph – just to clarify: do permissions for data collection have to be obtained BEFORE application submitted or can this be done once project starts?

Answer: As noted in Section I under the Approach header: Applicants should review relevant state laws, school district policies, and other administrative procedures of their sites or partner organizations to ensure the feasibility of data collection. If necessary, applicants should obtain any required permissions to collect these data. Applicants should demonstrate/indicate within the application that they have permissions to collect these data and report them to CDC as part of this project, as well as demonstrate the capacity to do so at the individual level. There are no exceptions or waivers from this requirement.

Question 25: I have a question about the format of the narrative. On pg 21 it refers to the SF424_RR guide for formatting but there are no instructions there about line spacing (e.g., single or double space is acceptable).

Answer: Formatting requirements are addressed in the SF424 (R&R) Application Guide(http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000). In the FOA 5. PHS 398 Research Plan Component; 8. Format for Attachments; the FOA States: 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).

Question 26: Can you please tell me roughly how many applications your office received in the last round of funding, and of those, how many were awarded? This will help me approximate the relative competitiveness of the program.

Answer: This is a new funding opportunity announcement. This RFA has not been published previously.

Question 27: Can the PI be a contractor or subcontractor?

Answer: The FOA does not specify the role/relationship of the PI to the applicant organization. In the Executive Summary of the FOA it states:

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. 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.

Question 28: If an applicant is from a large tri-state area, a large region, should we specify a subsection of that area?

Answer: It is up to the applicant to determine the setting for the study. Part 2. Full Text of the FOA provides the intent of the FOA regarding target population, population size, etc.

Question 29: Will funding decisions be made together with review of all OAH teen pregnancy prevention FOAs or in a separate timeline?

Answer: To prevent project overlap, applicants will only be funded once. In terms of timing, the review will be distinct from the other teen pregnancy prevention FOAs. CDC and OAH will collaborate, but applicants will only be funded once. As stated in the FOA under Key Dates, review of applications will be completed during May with award start dates of September 30, 2015.

Question 30: Regarding target audience, if we are focusing on 20-24 year olds, would we have to preclude those that do not/may not have teen partners?

Answer: There are no specifications in the FOA regarding the age of the participants' female partners for intervention outcomes or intervention target population. As noted on page 8 and 11 in the FOA under the Approach section:

The proposed intervention should be targeted to young men within the age range of 15-24 years who are at high risk for fathering a teen pregnancy.

The primary outcomes to be assessed are increased: condom use; abstinence from vaginal intercourse (primarily for teen males); use of sexual and reproductive health services; female partners' use of moderately effective contraception (hormonal injection; patch; ring; pill) or highly effective long-acting reversible contraception (implant; IUD); and dual use of condoms and moderately or highly effective contraception. The applicant should address possible limitations in assessing outcomes related to female-controlled methods of contraception (i.e., moderately or highly effective contraceptive methods), since these methods are not under the direct control of the male intervention participants. Measures will need to be designed to maximize reliability.

Question 31: Regarding the target population- must we focus on young males that have not fathered?

Answer: The FOA does not preclude having a target population t includes young men who have already fathered a pregnancy. As stated under "Purpose," "Interventions should target young men at high risk of fathering a teen pregnancy (e.g young men at risk of health disparities due to low socioeconomic status (SES), race/ethnicity [with respect to high pregnancy rates among female teens who are Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander, American Indian and Alaska Native], exposure to social determinants negatively affecting health [e.g., inadequate housing, lower educational attainment, stressful neighborhood environment, high community unemployment, etc.], being out of school [for young men under age 18], unemployment [for young men ages 18-24], living in foster care, homelessness, experiencing trauma or domestic violence, involvement with the criminal justice system, substance abuse)."

Also note under "**Section IV. Application and Submission Information", "**Describe the target population(s) for proposed intervention and their risk of fathering a teen pregnancy. Include information on: rates of fathering a teen pregnancy (if available) and/or teen pregnancy or birth rates in the locality of the study; STD rates (chlamydia, gonorrhea) of young men in the proposed target population; and behavioral determinants, cultural and social norms, and/or risk behaviors in the target population."

Question 32: Regarding methodology, will you only accept randomized controlled trials (RCTs)?

Answer: Under the "Approach" header, the FOA states, "The proposed evaluation plan should address the required elements outlined in the Evidence Review (http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx) (see Appendix A for a summary). Evaluations implementing randomized controlled trials (RCTs) are preferred, though rigorous evaluations with non-randomized designs that include an external comparison group are acceptable when an RCT is not feasible. Cooperative agreement recipients and Study Team partners will receive training and technical assistance from CDC on developing and implementing research protocols that meet HHS evidence standards.

Question 33: Will you post minutes from this call on the website?

Answer: Minutes from the pre-application calls will not be posted on a website. All answers will be posted in an amended FOA on Grants.gov 2-3 weeks prior to the application due date.

Question 34: A question about ownership- the FOA indicates that any product developed will be owned by CDC. Is this the case, such that the applicant would not retain rights to sell the intervention?

Answer: As per Page 60 of FOA Number: RFA-DP-15-007, the Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS, HHS/PHS, and applicable HHS/CDC policies. However, the Recipient Organization will provide CDC and OAH with final intervention package materials to reproduce, publish, or otherwise use the work for public health purposes, and to authorize others to do so in accordance with applicable grant regulations. Although CDC and OAH do not intend to sell or directly market any program developed under this award, CDC and OAH reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work developed under this award for Federal purposes and to authorize others to do so (45 CFR §§ 75.32-Copyrights).

CDC and OAH would like to showcase final program packages and evaluation results on their websites. The method of posting the final program package on their websites would be read-only. **Persons interested in learning more about the program or in obtaining materials or training would be directed to the appropriate contact (e.g., developer, publisher, supplier, etc.)**

Question 35: Relating to adaptation, FOA says that those programs previously listed in evidence review for HIV cannot be submitted. But what if the population and age range were changed as well as the intervention, would it then be eligible?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted in the FOA Section I under the "Background and Purpose" header, Component B of the FOA allows for applicants to have a partially developed intervention to be completed prior to the

evaluation. Successful applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials. Under this component, interventions will not be implementation-ready at the time of application; applicants will have up to 18 months from notice of award to finalize the intervention, including detailed intervention materials, (e.g. logic model, core elements, curricula, training manuals) prior to implementation and rigorous evaluation.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 36: How many schools can you work with, in terms of the minimum amount of young men needed?

Answer: As noted under the Content and Form of Application Submission, "Describe power analyses conducted to determine the appropriate sample size for evaluating the intervention in the target population. The study should be powered to detect change in key outcomes (e.g., condom use, abstinence from vaginal intercourse, female partners' use of 24 of 59 moderately or highly effective contraceptive methods)."

Question 37: What will the total award amount be?

Answer: The Executive Summary states, "The estimated total funding, covering both direct and indirect costs for the entire project period, for Component A and Component B combined, is $10,000,000. The intent is to commit a total of approximately $2,000,000 (direct and indirect) for the first 12-month budget period for two (2) to three (3) 5-year research projects, with at least one project evaluating an intervention targeted at young men aged 15-19 years. Two to three grantees will be awarded $666,000 to $1,000,000 (direct and indirect) costs in FY2015. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size of each award may vary. The total amount awarded and the number of awards will depend upon the number, quality, and cost of the applications received. However, the total number of grantees will not exceed three and the total funding amount will not exceed $2,000,000 in FY2015. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications."

Question 38: Regarding the letter of intent, will the letter of intent be used as a prescreening?

Answer: No, the letters of intent are only for planning purposes for the review, as referenced in the FOA in Section IV. Application and Submission Information, 3. Letter of Intent. Applicants should identify the specific component for which they are applying to aid CDC in planning.

Question 39: Regarding eligibility of the study team- the intervention developer, research firm, and evaluator- can each come from any type of institution?

Answer: The FOA does not specify the role/relationship of members of the study team to the applicant organization nor does it specify the types of institution that the study team may be affiliated with. The FOA does provide guidance on the institutions/organizations that are eligible to apply and submit an application and on the eligibility of the PD/PI:

In the Executive Summary of the FOA it states:

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. 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.

Question 40: Regarding the length of the submission, the FOA states a 25 page limit for the research strategy, but are there page limits on the other sections?

Answer: Yes, there are page limits to be aware of when completing your application. Please refer to the SF424(R&R) Application Guide for application instructions, including information on page limits. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions. Helpful sections of the Guide are 5.0 Completing PHS 398 Forms and 5.5 PHS 398 Research Plan Form.

Question 41: Our intervention, Wise Guys, is not listed in Appendix 2 under programs currently being evaluated under OAH Prep, but it is our understanding that Mathematica is currently conducting a rigorous evaluation of Wise Guys with PREP funding in Iowa - https://clinicaltrials.gov/ct2/show/NCT02052830 Is our intervention, WiseGuys, an eligible intervention for CDC RFA-DP-15-007?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question.

The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings). In addition, as noted in Section I under the Approach header, the proposed intervention should fill a significant gap in evidence-based teen pregnancy prevention interventions.

As noted under Section III "Special Eligibility Requirements" header: the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

As noted in Section III "Responsiveness" header: "Applicants for Components A and B are required to include each of the following documents in Appendix A of the application. 1) Applications must include a letter from the intervention developer that describes a) the intervention, b) the intervention target population, and c) attests that the intervention is not on the list of interventions in Appendix A

does not simply replicate or make changes (adaptations) to an intervention in Appendix A; and has not been rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 42: I would like know if the selected intervention program under this grant has to be specific to males, or can it be an intervention that showed data with a larger proportion of those studied to be males?

Answer: We cannot comment on specific topics or approaches. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

This type of application would likely fall under Component B, because it was originally designed for females and males and would need to be designed for young men, specifically. As noted in the FOA on page 18 of the Special Eligibility Requirements: The proposed intervention must be targeted to young men. The intent of the FOA is to evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. As noted on page 23 of this FOA of the Research Plan Component, Applicants should describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population. Applicants should describe how the proposed intervention addresses risk and protective factors for teen pregnancy that are specific to young men.

As noted in the FOA on page 6 in the Background and Purpose section, successful Component B applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials.

As noted on page 18 of the FOA, under the Special Eligibility Requirements, the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A.

Question 43: I am writing regarding the application sections/page limits for the FOA number RFA-DP-15-007. The application packet highlights required fields to upload: Research strategy; Budget justification; Biographical Sketch; Project Summary Abstract; and Project Narrative. However, the FOA (p. 23) is asking for: Introduction/background; Specific Aims; Research Strategy (no more than 25 pages) with many components, including Part I- intervention, study design, study implementation, study dissemination, study management, and Part II Training and Technical Assistance. Can you assist me with the desired structure for the submission

Answer: Please refer to the SF424(R&R) Application Guide for application instructions and forms. The application must follow the structure as described in the Guide. A key part of the application is the PHS 398 Research Plan. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions. Helpful sections of the Guide are 5.0 Completing PHS 398 Forms and 5.5 PHS 398 Research Plan Form.

In the FOA, Section IV, 5. PHS 398 Research Plan Component section depicts the 16 sections of the PHS 398 research plan that applicants should address as part of their application. Following the 398 Research Plan Components in that Section, the FOA provides detailed guidance on what should be addressed in an application. This detailed guidance is referred to as the research plan and it outlines the topics that should be addressed in the application; these headings include Introduction/background, Specific Aims, Research Strategy, and subheadings Part I: Implementation and Evaluation, and others. Typically, most of the detailed information is included in the Research Strategy section of the application, but this is determined by the applicant.

Question 44: On Page 27 Number 7. Page Limitations – FOA states "the research strategy component of the research plan narrative is limited to 25 pages." (Also stated on page 2 in the "Note") Does the research plan narrative refer to the Project Narrative?

Answer: Please refer to the SF424 (R&R) Application Guide for application instructions and forms. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions. The section of the Guide which addresses the Project Narrative is 4.4 Other Project Information Form, 8. Project Narrative (page I-77). The Project Narrative is a brief section describing the relevance of the research to public health. It is not the research plan. For information on the research plan, please see section 5.0 – 5.5 in the Application Guide.

Question 45: Is there a page limit for the Project Narrative?

Answer: Yes, there is a page limit for the Project Narrative. Please refer to section 4.4 Other Project Information Form, 8. Project Narrative (page I-77) of the SF424 (R&R) Application Guide. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions.

Question 46: FOA states that "Appendices may not exceed 10 PDF files with a maximum of 50 pages for all appendices." Is there a total page limit for the application? Would the total page limit include the 13 page application packet?

Answer: Please refer to the SF424(R&R) Application Guide for application instructions, including information on page limits. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions. Helpful sections of the Guide are 5.0 Completing PHS 398 Forms and 5.5 PHS 398 Research Plan Form.

Question 47: May a subcontractor be included on more than one application?

Answer: The applicant determines the research team as well as any other staff or other resources needed to accomplish the proposed project activities. The FOA does not specify any specific subcontractor requirements. Upon award, the budget will be reviewed to ensure all funds are specific, allocable, and don't represent any duplication in funding.

Question 48: We are exploring a potential grant application in collaboration with our local Coordinated Care Organization (CCO), which is X's version of an Accountable Care Organization.

We are interested in our CCO being the lead applicant and fiscal agent, but in looking at the eligible applicants listed in Section III.1 of the RFA, we did not see a category they would naturally fall under. Would they be an eligible applicant under this RFA?

Answer: This FOA is an open competition announcement. The full range of institutions and organizations are eligible to apply; the eligibility categories are listed in Section III. Eligibility Information.

Question 49: I have a question about the follow up period. Is it ok in the intervention if it finishes but if you have touch points during that time period so as not to lose touch with them. Is that okay?

Answer: Yes, that was simply a minimum requirement. The follow-up period begins after the last *intervention* contact. Contacts with both control and intervention groups to improve retention is not considered an intervention contact.

Question 50: Related to the earlier question, if done as a co-ed intervention previously, can we adapt an intervention to be designed for males?

Answer: We cannot comment on specific topics or approaches. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

This type of application would likely fall under Component B, because it was originally designed for females and males and would need to be designed for young men, specifically. As noted in the FOA on page 18 of the Special Eligibility Requirements: The proposed intervention must be targeted to young men. The intent of the FOA is to evaluate innovative interventions specifically designed for young males that fill a significant gap in the current list of evidence-based teen pregnancy prevention interventions. As noted on page 23 of this FOA of the Research Plan Component, Applicants should describe how the intervention includes innovative approaches to preventing teen pregnancy when intervening with young men, through aspects such as intervention approach, structure, content, and implementation. Examples include, but are not limited to: addressing cultural norms, gender equity, healthy relationships, economic and education opportunities and other social determinants of health; using multi-component approaches (e.g., clinical- and community-based partnerships); and using intervention delivery methods that are highly relevant to the target population. Applicants should describe how the proposed intervention addresses risk and protective factors for teen pregnancy that are specific to young men.

As noted in the FOA on page 6 in the Background and Purpose section, successful Component B applicants will have conducted formative research and/or consulted with members of the target population, initiated development of the intervention, and will have drafts of intervention materials.

As noted on page 18 of the FOA, under the Special Eligibility Requirements, the proposed intervention must not be on the list of interventions in Appendix A and does not simply replicate or make changes (adaptations) to an intervention in Appendix A and has not been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

Question 51: Can't find line spacing?

Answer: Line spacing is up to the applicant to determine. For other information on formatting requirements, please see the SF424 (R&R) Application Guide(http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)

Question 52: Budget submission. The application is due March 6. Is that when budget should be submitted?

Answer: Yes, complete applications are due on March 6. This should include all required documents as outlined in the application package and guidance.

Question 53: I am in the planning stages and am trying to figure out if I would fit under Component B.

Answer: To summarize from the FOA, Component B applicants would submit a partially developed intervention, it will not be implementation ready, grantees under this Component B would have 18 months to finalize; successful applicants will have some formative research or consulted with target population and will have started development and will have draft materials.

Question 54: I have a question about PI eligibility…we are a young organization, but our leadership has enrolled large numbers of participants in previous studies. But as a young applicant, can that experience be used to show skills?

Answer: Applicants need to be able to demonstrate capacity to recruit, regardless of where applicants got the experience. Please refer to Section III "Special Eligibility Requirements" for the required elements for the application, including PI experience.

Question 55: We are wanting to confirm that focusing on male sexual responsibilities does not preclude delivering the program/curricula in a co-educational context if: (1) we can make an theoretically based argument for including young women in the program delivery process, (2) we underscore that doing so will facilitate our capacity for reaching a larger and more representative group of young men, (3) we address all the requirements outlined in the instructions for applicants. Can you please confirm that the reviewers (scientific and program) are willing to consider a male focused program that is delivered within a co-educational context?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving organizations, correctional settings).

In the FOA, Section III Eligibility Information; 3. Special Eligibility Requirements the FOA states the proposed intervention must be targeted to young men. The target population refers to the intervention participants.).

Question 56: Is there a minimum and/or maximum number or males, ages 15-24 that must be reached with this grant?

Answer: The FOA does not indicate a minimum or maximum sample size. As noted in Section I under the Approach subsection, Applicants should provide a power analysis that demonstrates the proposed sample size after anticipated attrition is sufficient to detect an intervention effect, and that includes a sufficient post-intervention follow-up period to adequately assess outcomes of interest (at least 24 months for Component A and 12 months for Component B).

Question 57: X is writing a proposal to submit for RFA-DP-15-007 to do rigorous evaluation of Wise Guys. Y is also submitting for funding from the CDC to evaluate Wise Guys, but we have permission to submit our proposed intervention. Is this okay?

Answer: We cannot comment on specific topics or approaches or make eligibility determinations during the question and answer process. The topic of the research is up to the investigator, and the applicant must demonstrate how their research topic fits within the intent of the FOA. We can highlight the purpose of the FOA and highlight some sections of the FOA that may be relevant for your question. The purpose of the FOA is to rigorously evaluate innovative interventions designed for young men aged 15-24 years old to reduce their risk of fathering a teen pregnancy that can be feasibly implemented in target settings (e.g., clinics, schools, community settings, youth-serving

organizations, correctional settings).

As noted in section III under the Special Eligibility Requirements header, the proposed intervention must not have been rigorously evaluated or currently being rigorously evaluated (i.e., a randomized-control trial or non-randomized design with external comparison group).

In addition, as noted in Section V under the Review and Selection Process header:

Funding preference may be used to achieve variation in funded projects based on:

- Type of setting (including, but not limited to clinics, schools, community settings, youth-serving organizations, correctional settings)

  Intervention approach (including, but not limited to: knowledge/skills/attitudes-based; youth development; social norms change)

- Target population age. The intent is to fund at least one award targeting young men within the age range of 15-19, and to fund a range of age groups.

To prevent project and funding overlap, same (or significantly similar) projects submitted through this FOA or any of the following funding opportunities available from the HHS Office of Adolescent Health's Teen Pregnancy Prevention Program: (Capacity Building to Support Implementation of Evidence-Based TPP Programs (OAH-15-0003); Implementing Evidence-Based Teen Pregnancy Prevention Programs to Scale in Communities with the Greatest Need (OAH-15-0004); Supporting and Enabling Early Innovation to Advance Adolescent Health and Prevent Teen Pregnancy (OAH-15-0006); Rigorous Evaluation of New or Innovative Approaches to Prevent Teen Pregnancy (OAH-15-0007)), will be funded only once.).

Question 58: On page 26 of the FOA it says, "Describe plan to and attend a 2-3-day project launch meeting in Year 1." Is this a meeting that CDC would arrange and we would go to Atlanta to attend? If so, who is expected to attend? Or is this a meeting that the grantee would arrange?

Answer: The PD(s)/PI(s) will have the primary responsibility for attending the 2-3 day project launch meeting in Year 1and should include expected costs in the budget of their application. This meeting will be arranged by CDC. Location is not yet determined.

Question 59: If component B is granted -at what point will the applicant receive funding?

Answer: The project period start date is September 30, 2015. Grantees will receive their Notices of Award (NoA) prior to the start date. The NoA will provide instructions regarding the payment system and preparations for receiving federal funds.

Question 60: Component A – Interventions - does the intervention(s) have to be created by us, or can we use another applicants statistics/interventions?

Answer: We cannot comment on particular topics or approaches during the question and answer process. However, we can point applicants to sections of the FOA. Under "Approach," the FOA states: "Applicants must demonstrate capacity and experience accessing and working with large groups of young men, including evidence of successful enrollment in programs, intervention studies or trials, and the expertise to implement the intervention with fidelity and conduct a rigorous evaluation. Applicants may use partnerships to fulfill the capacity needs for successfully completing the project (e.g., intervention developer collaborating with a clinic and/or youth-serving organization to develop and implement the intervention; partnering with a research firm to conduct the evaluation). The applicant PI(s) and their primary partners will hereafter be referred to as the Study Team."

Further, under “Special Eligibility Requirements,” the FOA requires applicants to, “Document that the intervention developer(s) (if different from the PI) a) permits the use of the intervention for the study evaluation, and b) agrees to provide CDC and OAH with final intervention package materials,” and “Document that the principal investigator or a member of the research team has been the principal investigator or co-principal investigator on at least one study that involved a rigorous evaluation of an intervention.”

Question 61: I am listed as the PI and we are planning to list Dr. X as a co-investigator. She is colleague here at X. She has that experience and the experience with randomized control trials. I have the male health expertise. Would it be advised to name her a co-principal investigator or are would it be ok to name here a co-investigator?

Answer: The FOA does not specify the role/relationship of members of the study team to the applicant organization nor does it specify the types of institution that the study team may be affiliated with. The decision of roles and responsibilities within the study team rest with the applicant. Please note that the FOA does provide guidance on the eligibility of the PD/PI:

Under “Special Eligibility Requirements,” the FOA requires applicants to, “Document that the intervention developer(s) (if different from the PI) a) permits the use of the intervention for the study evaluation, and b) agrees to provide CDC and OAH with final intervention package materials,” and “Document that the principal investigator or a member of the research team has been the principal investigator or co-principal investigator on at least one study that involved a rigorous evaluation of an intervention.”

Additionally, under “Approach,” the FOA states: “Applicants must demonstrate capacity and experience accessing and working with large groups of young men, including evidence of successful enrollment in programs, intervention studies or trials, and the expertise to implement the intervention with fidelity and conduct a rigorous evaluation. Applicants may use partnerships to fulfill the capacity needs for successfully completing the project (e.g., intervention developer collaborating with a clinic and/or youth-serving organization to develop and implement the intervention; partnering with a research firm to conduct the evaluation). The applicant PI(s) and their primary partners will hereafter be referred to as the Study Team.”

Question 62: We are planning our intervention group to have the computer assisted motivational interviewing modules on sexual and reproductive health issues. We were planning to have our control group to have computer assisted motivation interviewing modules on fitness issues ¬ improving diet, increasing exercise, and decreasing/stopping smoking of tobacco.

Would it be advised to choose a control group focus to related to sexual and reproductive health issues in a different modality like “standard” in-person group sessions to discuss similar topics -- condom use, contraception, use of services -- or is it ok to have the control address separate topics ¬ diet, exercise, and tobacco use?

Answer: We cannot comment on particular topics or approaches during the question and answer process. We can, however, point applicants to sections of the FOA that may be relevant.

As stated in section I under the Approach header, the proposed evaluation plan should address the required elements outlined in the Evidence Review (http://tppevidencereview.aspe.hhs.gov/EvidencePrograms.aspx) (see Appendix A for a summary).

And, as stated in Section V, under the “Approach” header,

Study design:

- Does the applicant propose a strong evaluation design for either a randomized controlled trial or a non-randomized design with an external comparison group? If the applicant proposes a non-randomized design, do they provide a compelling justification?
- Does the applicant have a reasonable plan to reduce bias in the evaluation?
- Does the applicant include plans to measure key outcomes?
- Does the applicant provide power calculations demonstrating that the proposed sample size, taking into account anticipated attrition and the unit of randomization is sufficient to detect intervention effects on main study outcomes in the target population?
- Does the evaluation design include assessments at baseline data and at subsequent time points during a minimum post-intervention follow-up period of 24 months (Component A) or 12 months (Component B)?
- Does the applicant provide an appropriate statistical approach to determine the efficacy of the intervention?
- If any aspects of the study design are incomplete due to applicant's need for training or technical assistance in addressing it, is this need included in the TTA plan?

Question 63: The best consultant/contractor to ensure fidelity of motivational interviewing is a business out of the U.S. Are we allowed to contract with them given that they are based in X country?

Answer: In Section III. Eligibility Information, 2. Foreign Organizations, the FOA states that "applicants may not include collaborators or consultants from foreign institutions." This indicates that federal funds from an award under this domestic FOA cannot be used to support a contract with someone from a foreign institution.

Question 64: I want to clarify that the "Introduction to Application" (page 22 of 59) and the "Introduction/background" (page 23 of 59) are different, and to confirm that we would not write an "Introduction to Application" and we would write a "Introduction/background".

Answer: In the FOA Section IV. Application and Submission Information, #5 "PHS 398 Research Plan Component," the 16 sections of the PHS 398 are outlined. Section 1. Introduction to Application is for Resubmissions and Revisions—this section should not be included in your new application. In the FOA, following the "PHS 398 Research Plan Component," is a detailed section providing guidance on what should be addressed in an application. This guidance includes a heading "Introduction/background"; information addressing "Introduction/background" should be included in the application, but it is at the discretion of the PI to determine location in the application. The similarity in language in these two sections may have led to this potential confusion. Please note: all applicants are encouraged to refer to the SF424(R&R) application guidance for more information.