U.S. Department of Health and Human Services

Office of Population Affairs

Notice of Funding Opportunity: Teen Pregnancy Prevention Tier 2 Rigorous Evaluation Cooperative Agreements

Opportunity Number: AH-TP2-23-001

Application Due Date:
05/17/2023 at 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

The Office of the Assistant Secretary for Health, Office of Population Affairs

FUNDING OPPORTUNITY TITLE

Teen Pregnancy Prevention Tier 2 Rigorous Evaluation Cooperative Agreements

ACTION

Notice

ANNOUNCEMENT TYPE

Initial CA (Cooperative Agreement)

FUNDING OPPORTUNITY NUMBER

AH-TP2-23-001

ASSISTANCE LISTING NUMBER AND PROGRAM:

93.297 , Teen Pregnancy Prevention

DATES

Application Deadline: 05/17/2023 by 6:00 PM Eastern.

Technical Assistance Webinar: 03/20/2023 at 3:00 PM Eastern.

EXECUTIVE SUMMARY

The Office of Population Affairs announces the availability of funds for Fiscal Year (FY) 2023 under the authority of Division H, Title II of the Consolidated Appropriations Act, 2023 (Public Law No. 117-328).

This notice solicits applications for projects that will rigorously evaluate promising interventions for preventing unintended teen pregnancy, sexually transmitted infections (STIs), behavioral risk factors underlying teen pregnancy, or other associated risk factors. Evaluating promising interventions includes developing, replicating, refining, and testing additional models and innovative strategies for preventing unintended teenage pregnancy. The goal of this initiative is to identify effective interventions for future replication by adolescent health practitioners and youth-serving professionals, and to disseminate the research findings and lessons learned to inform future studies. Applicants should propose rigorous impact evaluations that are either randomized control trials (RCTs) or quasi-experimental designs (QEDs) with a comparison

condition. To ensure health equity, OPA is particularly interested in evaluations of promising interventions in populations and settings with great need and with significant health disparities. OPA anticipates funding a wide range of adolescent health innovations under this opportunity. All interventions proposed for evaluation under this initiative should already have compelling, positive preliminary evidence from previous research and demonstrated support from previous participants and communities. OPA expects the intervention to fit the population and setting proposed for the application.

OPA intends to make available approximately $11.475 million for an estimated 11-15 awards. The amount of funding an applicant may request ranges from $500,000 to $1,000,000 per year for a period of up to five years (five 12-month budget periods). Awards may have a period of performance of up to 5 years. Funding for budget periods after the first will be based on the availability of funds, satisfactory progress of the project, grants management compliance, and continued best interests of the government.

The Office of the Assistant Secretary for Health (OASH) encourages all applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that their applications comply with all requirements and instructions.

Table of Contents

A. Program Description

The Office of Population Affairs announces the availability of funds for Fiscal Year (FY) 2023 under the authority of Division H, Title II of the Consolidated Appropriations Act, 2023 (Public Law No. 117-328).

The primary focus of OASH is leading America to healthier lives, especially for those who have suffered historic disparities. In support of this vision, OPA promotes health across the reproductive lifespan through innovative, evidence-based sexual and reproductive health and family planning programs, services, strategic partnerships, evaluation, and research. The Teen Pregnancy Prevention (TPP) program is a national, evidence-based program that funds diverse organizations working to reach adolescents to improve sexual and reproductive health outcomes and promote positive youth development.

The TPP program supports medically accurate, age-appropriate, and complete programs to reduce unintended teen pregnancy, sexually transmitted infections (STIs), behavioral risk factors underlying teen pregnancy, or other associated risk factors (such as, but not limited to, initiation of sexual activity, frequency of sexual activity, number of sexual partners, contraceptive use, substance use, intimate partner violence (IPV)). The TPP program supports numerous rigorous, independent evaluation studies that significantly contribute to the field's knowledge of where, when, and with whom programs are most effective. To continue expanding the evidence base and addressing the changing needs of youth and communities, the TPP program replicates, refines, develops, tests, and evaluates promising interventions, additional models, and innovative strategies to advance adolescent health, by preventing unintended teen pregnancy and risk factors underlying or associated with teen pregnancy.

The purpose of this initiative is to fund rigorous impact and implementation evaluation of promising interventions for preventing unintended teen pregnancy, STIs, behavioral risk factors underlying teen pregnancy, or other associated risk factors. Through the awards, OPA aims to identify effective interventions for replication by adolescent health practitioners and youth-serving professionals, disseminate the research findings and lessons learned to inform future studies, and ultimately expand the knowledge base for TPP programming. This funding will support rigorous evaluations designed to answer important research question(s) about the impact and implementation of TPP interventions.

1. Background

In 2020, the U.S. teen birth rate (measured as births per 1000 females ages 15-19), was 15.4 (Centers for Disease Control and Prevention Vital Statistics, 2020). The U.S. teen birth rate is higher than that found in most developed countries (Sedgh G., 2015). Persistent disparities in U.S. teen births exist by race and ethnicity. In the U.S., birth rates are higher among American Indian/Alaska Native (AI/AN), Black, Hispanic, and Native Hawaiian and Pacific Islander (NHPI) adolescents than among teens overall. In 2020, AI/AN adolescent females had the highest birth rate (25.7), followed by Black adolescents (24.4) (Centers for Disease Control and Prevention Vital Statistics, 2020).

Beyond racial and ethnic disparities, some adolescents experience higher rates of unintended pregnancy and births than others. For example, young women living in foster care are more than twice as likely to become pregnant than young women not in foster care (James, 2009). Youth involved in the juvenile justice system experience higher rates of risky sexual behaviors compared to their non-system involved peers and are at higher risk for pregnancy and parenting (Sedlak, 2010). Adolescent lesbian and bisexual females are more likely to have ever been pregnant than their heterosexual peers (Saewyc, 2014).

In the U.S., teens and young adults, ages 15 to 24, account for nearly half of all new cases of sexually transmitted infections (STI) (Centers for Disease Control and Prevention S., 2020). Persistent and noteworthy disparities exist by race, ethnicity, geography, and among those that have been historically underserved, marginalized, and adversely affected by persistent

poverty. Young gay and bisexual males have disproportionately high rates of HIV, syphilis, and other STIs (Centers for Disease Control and Prevention S., 2020).

We aim to equitably bolster adolescent health outcomes and advance health equity through the development, evaluation, and dissemination of new and innovative approaches. Health equity is: "The attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities" (Healthy People, 2030; Office of the Assistant Secretary for Health/Office of Disease Prevention and Health Promotion., 2022). Advancing health equity in teen pregnancy prevention will require sustained, multi-pronged, multi-level interventions and strategies that are both innovative and evidence based. It also requires projects to be greatly attuned to the needs of their community and population to fully understand what inequities exist and the underlying causes contributing to them. Through this deep examination, projects can then work toward providing user-centered, high-quality programming and services that improve sexual and reproductive health outcomes and promote positive youth development.

To date, the HHS Teen Pregnancy Prevention Evidence Review (TPPER) has identified 48 programs with evidence of effectiveness; most of these effective programs are implemented in school-based settings and used with general populations in-person (Lugo-Gil, et al., 2018). To ensure health equity, we are particularly interested in rigorous evaluations of promising interventions in populations and settings with great need and with significant health disparities. This may include, but is not limited to, interventions in juvenile justice or foster care/child welfare settings, with expectant and parenting youth, youth with disabilities, with youth experiencing homelessness, or male-identifying youth. We recognize that in-person, school-based programming for general populations may not fully reach the youth who experience disproportionate rates of unintended teen pregnancy; therefore, we also are interested in evaluating TPP interventions that are self-paced and self-delivered, such as technological interventions as well as short-duration programs. Additionally, we are interested in funding projects that potentially impact not only individuals but also the communities and systems within which individuals are situated.

We seek evaluations of interventions that address key adolescent health disparities and have the potential to make a significant contribution to preventing unintended teen pregnancy. We anticipate funding a wide range of adolescent health innovations under this funding announcement; the eligible interventions may include, but are not limited to, programs, curricula, clinical interventions, technological interventions, systems-level interventions, community-level approaches, and others. Interventions may work directly with adolescents, their caregivers, and/or with youth-serving professionals to address adolescent health behaviors relevant to teen pregnancy prevention. We expect any intervention proposed for evaluation under this initiative to already have compelling, positive preliminary evidence from previous formative evaluation and prior research, including documented effects on intended outcomes. We expect the intervention to have demonstrated support from previous participants and communities. The intervention should fit the population and setting proposed for the application. Interventions should have a clearly described theory of change and logic model (See Section 2.a.).

TPP Interventions rigorously evaluated previously under federal funding are not appropriate for this funding unless significant changes have been made to the intervention to address findings from the previous evaluation results. Interventions that are not appropriate for this funding unless significantly adapted include any interventions implemented and evaluated under the following awards:

- Phase 2 Rigorous Evaluation of Promising TPP Interventions (TPP20 Tier 2 Phase 2) – (https://opa.hhs.gov/grant-programs/teen-pregnancy-prevention-program-tpp/tpp-grantees/current-tpp-grantees),
- Rigorously Evaluating New TPP Approaches (Tier 2b) – 2015-2020 (https://opa.hhs.gov/grant-programs/teen-pregnancy-prevention-program-tpp/tpp-grantees/past-tpp-grantees-2015-2020),
- TPP FY2010 Tier 2 Research and Demonstration (https://opa.hhs.gov/sites/default/files/2020-07/summary-researchdemonstration.pdf), and
- Personal Responsibility Education Program Innovative Strategies (PREIS) funding (FY2010, FY2015, FY2019) (https://www.acf.hhs.gov/fysb/grant-funding/personal-responsibility-education-innovative-strategies-preis-grantee-profiles)

Interventions identified as effective by the HHS Teen Pregnancy Prevention Evidence Review (TPPER) are also not appropriate for this funding (https://tppevidencereview.youth.gov/FindAProgram.aspx), unless significant adaptations are proposed to the intervention, ultimately creating a new intervention. Minor changes to an Evidence-Based Program (EBP) to improve its fit and relevancy are more appropriate within TPP Tier 1 replication initiative awards (AH-TP1-23-001). Major changes to an Evidence-Based Program (EBP) that substantially change the model's core components, logic model, or delivery mechanism in a manner that changes the intended outcomes are appropriate for rigorous evaluation under this NOFO. The NOFO supplemental materials (Section I) include a complete list of interventions that are not eligible without substantial modification.

2. Expectations for Funded Projects

Award recipients under this announcement should meet each of the below expectations in the execution of their funded project:

a. Implement Promising Interventions

We expect projects to evaluate interventions for the purpose of preventing unintended teen pregnancy, reduce STIs among adolescents, address behavioral risk factors underlying teen pregnancy, or address other associated risk factors for unintended teen pregnancy. We encourage recipients to target resources to populations disproportionately impacted by unintended teen pregnancy and STIs, to reduce health disparities and thereby achieve greater equity in adolescent health. In addition, we expect selection of interventions that fill gaps in the existing evidence base, including interventions that use different modalities for implementation (e.g., self-paced, technology, non-school settings) and interventions that impact not only individuals but also the communities and systems within which individuals are situated.

We expect recipients to implement interventions that have compelling, positive preliminary evidence from previous formative evaluation and prior research, including documented effects on intended outcomes. The recipient's chosen intervention(s) should have demonstrated support from previous participants and communities. The intervention should be a good fit for the population and setting proposed for the application. Interventions should have a clearly described theory of change and logic model. Projects should not duplicate interventions that have already been rigorously evaluated and published on the OPA website.

This opportunity is for research and demonstration projects, and not service delivery. Service delivery may be incidental or ancillary to the project but service delivery is not the primary purpose of this initiative. Other than piloting, we do not expect recipients to implement the intervention with participants who are not in the study sample.

b. Conduct Rigorous Evaluation of the Intervention

We expect all recipients to conduct a rigorous impact and implementation evaluation of their proposed intervention. We expect rigorous impact evaluations to have the most robust possible design that is feasible for the intervention in the setting and with the intended population. When feasible, we expect the evaluation design to meet the criteria for the quality of an evaluation study per the criteria in the HHS Teen Pregnancy Prevention Evidence Review (TPPER), version 6.0. (https://tppevidencereview.youth.gov/ReviewProtocol.aspx). TPPER is a systematic process for reviewing evaluation studies against a rigorous standard to identify programs with evidence of effectiveness in reducing teen pregnancy, STIs, or associated sexual risk behaviors. TPPER defines the criteria for the quality of an evaluation study and the strength of evidence for a particular intervention. HHS recently updated the evidence review standards in Fall 2022. Recipients may collect additional outcomes beyond those recognized currently by the TPPER, as long as at least one of the study outcomes is a sexual risk behavior, and the other outcomes collected are "associated risk factors" clearly associated with unintended teen pregnancy.

We expect recipients to conduct either randomized control trials (RCTs) or quasi-experimental designs (QEDs) with a comparison group.

- RCTs are experiments that randomly assign participants into different, unique groups: the treatment group and the comparison. We expect all recipients conducting randomized evaluations to use the intent-to-treat (ITT) framework for primary analyses. In an ITT framework, evaluators compare the participant outcomes between the individuals assigned to receive the intervention and those not assigned to the intervention (ACF OPRE, 2016).
- QEDs form intervention and comparison groups through methods other than random assignment of participants. Researchers use QEDs for impact evaluations when random assignment is not feasible. QEDs include methods such as Propensity Score Matching (PSM), Regression Discontinuity Designs (RDD), and Interrupted Time Series (ITS) (ACF OPRE, 2016).

Recipients may conduct either efficacy or effectiveness studies. Efficacy studies evaluate interventions under ideal conditions, often with the close involvement of the intervention

developer, whereas effectiveness studies evaluate an intervention during routine or natural conditions (ACF OPRE, 2016).

Recipients may conduct supplementary analyses in addition to the rigorous impact and implementation evaluations. These additional analyses may include cost studies, qualitative data analyses, or core components analyses. We strongly encourage testing of the core components as part of the rigorous evaluation.

We expect recipients to have a detailed evaluation design finalized by the end of the planning period. We expect that all studies shall have a counterfactual, and there will be equivalency between the study groups at baseline. Additionally, we expect the programming received by the study groups to be different enough to allow for a meaningful test. We expect recipients to register their studies with an online registry such as clinicaltrials.gov.

We expect recipients to have a data collection plan finalized by the end of the planning period. We expect recipients to collect and analyze outcomes that are relevant to the intervention's logic model and proposed research questions. Recipients should include at least one sexual behavioral outcome. We expect recipients to collect all study data during the period of performance. We anticipate that recipients will collect survey data at baseline, at one short term follow-up (e.g., between 0 months-1-year post-intervention), and at one long-term follow-up (e.g., 9 months or more post-intervention). Recipients should justify any additional data points proposed beyond these three points and discuss feasibility and necessity with us after award, during the planning period. We expect recipients to submit an analysis plan to us for review and feedback during the third year of funding; we will provide templates during that year. We expect recipients to use the final 6-9 months of the award for data analysis and reporting. We expect recipients to submit a final evaluation report to us summarizing their evaluation findings and lessons learned. We will review and provide feedback on this report.

We expect recipients to monitor and report to us on their progress recruiting, consenting, and retaining study participants. We expect recipients to make steady and consistent progress toward enrolling their study sample during each year of their award. A general benchmark is to enroll at least 25% of the sample by the end of year 2, at least 50% of the sample by the end of year 3, at least 75% of the sample by the end of year 4, and reach 100% of the sample size during year 5. We expect recipients to meet the TPPER standards for attrition (TPPER protocol, version 6.0, Section C.2 on pp. 5-7).

We expect recipients to address limitations, bias, and possible threats to internal and external validity within their studies. Recipients should conduct their studies through a credible and neutral process, which includes, at a minimum, evaluation staff who do not have perceived or actual conflict of interest and can remain independent of the intervention. We strongly encourage use of an independent, external evaluator.

As a condition of the award, we require recipients to participate in ongoing OPA-sponsored Evaluation Technical Assistance. Further, as a condition of the award, we expect recipients to participate in an OPA-directed Federal evaluation, if selected and funding for such an evaluation becomes available.

c. Participate in a planning and piloting period

During the first 6 - 12 months of the award, recipients will engage in a planning and piloting period. During the planning and piloting period, we expect recipients to work closely with us to refine, improve, and finalize the evaluation design and methods. We expect recipients to finalize the intervention materials and ensure that the intervention is a good fit for the participants using end-user feedback.

In addition, during the planning and pilot period, recipients should obtain any necessary Institutional Review Board (IRB) approvals for the evaluation. The duration of the planning period is contingent upon each recipient's demonstrated readiness but should not exceed 12 months. By the end of Year 1, we expect that all recipients will be ready to begin the evaluation. Failure of a recipient to receive OPA approval for their evaluation plan or make satisfactory progress toward completion of planning period milestones by the end of year one may impact funding for Year 2 (Section F.17.e).

Recipients should complete key milestones during the planning and piloting period to ensure readiness for full implementation of the study, such as:

- training staff;
- ensuring that the project implementation sites are not duplicative of other TPP-funded projects;
- finalizing agreements with all key partners and subrecipients;
- obtaining OPA approval of the evaluation design and instruments;
- completing the OPA materials review process (see Section A.2.d.);
- pilot-testing intervention materials to incorporate user-feedback, demonstrate desirability, and ensure fit and appropriateness;
- pilot-testing evaluation instruments and procedures;
- finalizing instruments and obtaining approval(s) from an Institutional Review Board (IRB).

d. Complete OPA Material Review

Recipients must ensure that all materials delivered to study participants are medically accurate and age appropriate. We also expect recipients to ensure that all materials are complete, culturally and linguistically appropriate, trauma-informed, user-centered, and inclusive of all youth. Project materials include intervention and comparison group materials, such as but not limited to curricula, facilitator manuals, participant manuals, videos, podcasts, posters, scripts, participant booklets, pamphlets, and handouts. We expect recipients to demonstrate that subject-matter experts have reviewed materials in relevant areas (e.g., age appropriateness). Recipients must make any necessary changes to materials prior to implementation. We expect recipients to inform us of their review process, findings, and plans to address any issues identified during the planning period. We expect recipients to submit for review and approval prior to implementation

any changes made to the intervention to address issues identified during materials reviews for medical accuracy, age appropriateness, completeness, cultural and linguistic appropriateness, trauma-informed approaches, user-centeredness, and inclusivity. We also expect recipients to submit all program materials for a medical accuracy review. Recipients may not begin implementation with the materials until after OPA has approved the use of the materials. We expect recipients to finalize all intervention materials prior to beginning the rigorous evaluation. Once the evaluation has begun, recipients should not make major changes to the intervention materials to avoid negatively impacting the evaluation.

e. Collaborate with Partners and Maintain Organizational Capacity

We expect recipients to use partnerships to fulfill capacity needs and successfully complete the project. Recipients and key partners should have the collective expertise necessary to successfully accomplish the goals and objectives for the overall project. We expect recipients will engage key partners in the project and maintain a collaborative environment. Each recipient is responsible for ensuring all partners meet the project expectations successfully and fulfill their roles. Recipients should assess the professional development needs of project staff on a regular basis and ensure that staff have the training needed to complete their roles in the project. We expect recipients to collaborate, coordinate, and share information with other OPA recipients, as appropriate, to prevent unnecessary duplication of activities, and ensure sharing and best use of available resources across funded projects.

f. Engage Participants in Ongoing Project Planning and Implementation

We expect recipients to engage the intended population in planning and implementing the project. Members of the intended population should provide ongoing input into the planning, implementation, and evaluation of the intervention to ensure that the project addresses their needs, fills existing gaps, does not duplicate programs or services already available, and is a good fit for the population, setting, or community(ies). Members of the intended population should also provide feedback to ensure that the intervention is relevant and likely to resonate with their peers. Finally, recipients should consult members of the intended population when developing messaging about project findings and branding or packaging intervention materials for dissemination.

g. Monitor and Improve the Project

We expect recipients to monitor the overall project and, make ongoing improvements to the project based on key findings. This could include improvements to either the evaluation or implementation procedures, for example.

We expect recipients to conduct an implementation evaluation designed to answer questions about intervention delivery during the study. At a minimum, we expect the implementation evaluation to address dosage, fidelity, quality, context, and counterfactual experience (Office of Adolescent Health, 2017). We expect recipients to conduct periodic monitoring of the programs and services offered within study sites and communities by other organizations to ensure that the project does not duplicate other services, and that the study clearly accounts for the experiences

of the comparison group. In addition, recipients must monitor the progress of participant enrollment, consent, and retention within the study as described in the rigorous evaluation expectations (Section A.2.b).

The monitoring process must include performance measures specific for the awarded project. In addition, recipients must collect uniform performance measures and report to us on a semi-annual basis. Section I.6 includes a list of the draft measures (OMB #0990-0348 Expiration Date: August 2023, pending renewal). We will provide final measures for the TPP 2023 cohort during the first 6 months of the project. Recipients are required to obtain and document any necessary permissions to collect these data. Documentation may include formal agreements with partners (MOAs), consent forms from parent/guardians, copies of school district approvals, citation to state law, etc. to collect these data. Recipients may be required to provide the supporting documentation for review, on request. Recipients have the responsibility to ensure they have appropriate permissions to collect all required performance measure data prior to collecting the data. There are no exceptions or waivers for this requirement.

While implementing and evaluating some non-curricular approaches, such as technological innovations, systems-level, and community-level approaches, you may find that some OPA measures or constructs (e.g., such as dosage, fidelity, and quality) are not relevant to your intervention. If you identify a need to change a measure, you would need prior approval from OPA to use alternate or proxy measures for dosage, fidelity, and/or quality. We expect recipients to develop the measures that future implementors of the intervention could use to monitor fidelity, quality, and dosage, and include those in their final program package (Section A.2.h.). There are no exceptions or waivers for this requirement.

We expect recipients to determine whether the intervention implementation occurred as originally intended in the approved project. We expect recipients to monitor the dosage of the intervention participants receive. We expect recipients to establish and implement a fidelity monitoring process for the intervention. The process should include, at a minimum, collection of data on fidelity and quality of implementation, reviewing and analyzing the data on a regular basis, and using the data to make continuous quality improvements to the implementation of the intervention. We expect recipients to collect qualitative contextual data relevant to the environment in which the intervention is being developed. Recipients should observe a minimum of 10% of all intervention sessions and 100% of intervention facilitators for fidelity and quality on an annual basis.

Recipients implementing and evaluating some non-curricular approaches, such as technological innovations, systems-level, and community-level approaches, may find that some OPA measures or constructs (such as dosage, fidelity, and quality) are not relevant to their intervention. If a recipient identifies a need to change a measure, we require prior approval to use alternate or proxy measures for dosage, fidelity, and/or quality. Recipients must develop the measures that future implementors of the intervention could use to monitor fidelity, quality, and dosage, and include those in their final program package (Section A.2.h.).

h. Document and Package the Intervention

By the end of Year 5, successful projects should have documented the evaluated intervention with sufficient detail so that other organizations may replicate the intervention to scale. Recipients should provide us with a complete electronic package of the final implementation-ready intervention by the end of the project (see Section F.9 regarding intellectual property rights). Implementation-ready interventions must include all the necessary components that will allow someone other than the original developer to implement the intervention. To be implementation-ready, an intervention package must include clearly defined program materials and core components, define all necessary staff supports and training needed for implementors, and specify guidelines and tools for monitoring implementation fidelity and quality (see Section A.2.g). We will provide guidance to recipients during the first six months of the awards.

We expect recipients to articulate the core components of the intervention(s) they are evaluating. Articulating the components of the intervention will help fill knowledge gaps about what makes an intervention effective and which components drive successful programming. We strongly encourage recipients to test the core components as part of the rigorous impact evaluation described previously (Section A.2.b). We will provide all recipients with a TPP components checklist and instructions during the first six months of the award, and recipients must use the checklist to describe the components of their interventions at the end of the planning period. To complete the components checklist, recipients will describe the intended content of the intervention, the delivery mechanism and format, the staff delivering the content, the dosage of the intervention, the location for implementation, and features of the group intended to receive the intervention. Additional information about the core components checklist and expectations may be found within the resources section of the NOFO (Section I, Resources, Core Components).

Recipients must update the checklist at the end of the project. We expect recipients and their partners to develop a plan for distributing the intervention to others who might be interested in replicating it in the future; this plan should account for any training needed.

i. Disseminate Project Results

We expect recipients to develop and implement a plan for widely disseminating the results of the evaluation, including implementation evaluation results, impact evaluation results, lessons learned, successes, and challenges. We expect recipients to write a final evaluation report summarizing the key findings and lessons learned from their projects. The final evaluation report should be in the format of a journal article for a journal of the recipient's choice. We expect recipients to disseminate their evaluation findings and lessons learned through presentations at professional conferences.

In addition to the traditional methods of dissemination, we expect recipients to work with us to share findings broadly with key project partners, community members, youth-serving professionals, researchers, other OPA recipients, the public, and policymakers.

We expect the dissemination plan will include publication of at least one article in a peer-reviewed journal and presentations at professional conferences. When published, the article should be freely, immediately, and equitably accessible to the public. In addition to

disseminating information about the evaluation results, we expect recipients to develop a plan for disseminating information about the intervention to organizations who may want to replicate the intervention in the future.

3. Federal Agency Substantial Involvement

Recipients will receive funding under a cooperative agreement. A cooperative agreement is a form of assistance that allows for substantial involvement by federal agency. Additional details of the substantial involvement for awards made under this NOFO are described in Section B.3.

B. Federal Award Information

1. Legal Authority

Division H, Title II of the Consolidated Appropriations Act, 2023 (Public Law No. 117-328)

2. Award Information

We intend to make funds available for competing CA (Cooperative Agreement) awards.

We will fund awards in annual increments and generally for a period of performance up to 5 year(s), although we may approve shorter periods of performance. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors.

Recipients will be required to submit a non-competing continuation application for each budget period after the first. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

We anticipate offering a competing continuation for an additional budget period for the purpose of providing funding to support selected recipients in transitioning successful projects to sustainability. Funding available for this addition budget period is not guaranteed at all nor expected to be at the same level of previous budget periods.

Award Information

Estimated Federal Funds Available	$11,475,000
Anticipated Number of Awards	16
Award Ceiling (Federal Funds including indirect costs)	$1,000,000 per budget period

Award Floor (Federal Funds including indirect costs)	$500,000 per budget period
Anticipated Start Date	08/15/2023
Estimated Period of Performance	Not to exceed 5 year(s)
Anticipated Initial Budget Period Length	12 months
Type of Award	Cooperative Agreement
Type of Application Accepted	Electronic via Grants.gov ONLY unless an exemption is granted.

3. Federal Agency Substantial Involvement

Awards made under this NOFO will be cooperative agreements. A cooperative agreement is a form of assistance that allows for substantial involvement by the program office. Substantial involvement is in addition to the usual monitoring and technical assistance provided under a grant (e.g., assistance from the assigned Federal project officer, monthly conference calls, occasional site visits, ongoing review of plans and progress, participation in relevant meetings, provision of training and technical assistance). Substantial programmatic involvement for cooperative agreements under this NOFO may include:

- Approving key personnel changes, including the project director/principal investigator and lead evaluator, or others identified as essential in the proposal.
- Reviewing and approving of program materials prior to use in the project to ensure the materials are medically accurate, age appropriate, complete, culturally and linguistically appropriate, trauma-informed, user-centered, and inclusive of all youth,
- Reviewing progress at planning period milestones and providing approval to move forward,
- Advising on the evaluation design plan and, survey instruments prior to initiating the evaluation,
- Advising on the evaluation analysis plans prior to implementation,
- Advising on and acceptance of final evaluation report.

C. Eligibility Information

1. Eligible Applicants

Any public or private (profit or nonprofit) entity located in a State (which includes one of the 50 United States, District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands) is eligible to apply for an award under this announcement.

Faith-based organizations and American Indian/Alaskan Native/Native American (AI/AN/NA) organizations that are public or private entities are eligible to apply. Public or private community-based organizations are eligible to apply.

Examples of eligible Organizations include:

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

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget. If you voluntarily include cost sharing in your application, you must include in your budget narrative a non-federal sources justification as described in Section D.3.b.1.t or your application will be disqualified (Section C.4.k). Voluntary cost sharing is not expected for research applications. During the merit review of an application, cost sharing will only be considered in the overall review of the adequacy of the total proposed budget (Federal and non-Federal share) to support the project proposed.

Applications including cost sharing or matching, whether required or voluntary, that result in an award will include the cost sharing or matching commitment on the notice of award at the level proposed in the application. See Section D.3.b.1.s. Any change in the responsibility to provide cost sharing or matching at that level will require prior approval of the grants management officer.

Cost-Sharing or Matching may include any in-kind contributions necessary to the execution of the proposed project (45 C.F.R. § 75.306).

3. Other - Application Responsiveness Criteria

We will review your application to determine whether it meets the responsiveness criteria below. If your application does not meet the responsiveness criteria, we will disqualify it from the competition; we will not review it beyond the initial screening. The responsiveness criteria are as follows

There are no Other - Application Responsiveness Criteria.

4. Application Disqualification Criteria

If you successfully submit an application, the OASH Grants and Acquisitions Management (GAM) Division will determine whether your application is eligible according to section C.1 Eligible Applicants. If we determine your application fails to meet the criteria described below, we will disqualify it, that is, **we will not review it and will give it no further consideration**.

a. You must submit your application electronically via https://grants.gov/ (unless an exemption was granted by the grants management officer 2 business days prior to the deadline) by the date and time indicated in Section D.5 of this announcement.

b. If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.

c. You must complete the required forms in the application package: SF-424, SF-424A, SF-LLL, and Project Abstract Summary (Section D.2.a).

d. Your application must be submitted in the English language and must be in terms of U.S. dollars (45 C.F.R. § 75.111(a)).

e. Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points (Section D.2.a).

f. Your Project Narrative must not exceed 50 pages. The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables)(Section D.2.a).

g. Your total application (i.e., the Project Narrative plus Appendices) must not exceed 100 pages. The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables)(Section D.2.a).

h. Your Federal funds request including indirect costs must not be above the maximum indicated in Award Ceiling (Section B.2).

i. Your Federal funds request including indirect costs must not be below the Minimum indicated in Award Floor, if any (Section B.2).

j. Your application must meet the Other - Application Responsiveness Criteria outlined above (Section C.3).

k. If your application includes cost sharing (voluntary or required, Section C.2), you must include in your budget narrative a non-federal sources justification.

D. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at https://www.grants.gov/. You can find it by searching on the Assistance Listing (formerly CFDA) number shown on page 1 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

OASH Grants and Acquisitions Management Division

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a. Application Format

Your application must be prepared using the forms and information provided in the online application package. This includes but is not limited to:

- SF-424 Application for Federal Assistance
- SF-424A Budget Information for Non-Construction Programs
- SF-LLL Disclosure of Lobbying Activities
- Project Abstract Summary

We encourage individuals to use their full name (first, middle, last) on the Standard Forms and other documents such as résumés/curricula vitae/biographical sketches to distinguish them for verification in the System for Award Management exclusion records. Delays may result in award processing if full names are not provided.

Only one Project Director/Principal Investigator (PD/PI) will be named on any resulting award. You should clearly identify the individual in that role in your application. This individual should be the person who will be responsible for the programmatic aspects of the project if an award is made. A placeholder PD/PI is strongly discouraged because this may not present a clear picture for the review. Furthermore, once an award is issued a request for a change in PD/PI requires prior approval of the grants management officer (45 C.F.R. § 75.308(c)(1)(ii-iii)).

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C.4. The page limit does not

include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria.

You must double-space the Project Narrative pages.

Your application must be submitted in the English language and must be in the terms of U.S. dollars (45 C.F.R. § 75.111(a))

You should use an easily readable typeface, such as Times New Roman or Arial. You ***must*** use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices (Section C.4(f)-(g)) when printed on 8.5" X 11" paper as determined by OASH/GAM, the application will not be reviewed further. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

b. Appendices Format

Your appendices should include any specific documents outlined in Section D.3.c, under the heading "Appendices" in the Application Content section of this announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/curricula vitae, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

c. Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. Furthermore, if your project is funded, HHS will publish the abstract from your form on TAGGS.hhs.gov and USASpending.gov. The abstract may also appear on the program office website or other government website. Therefore, do not include sensitive or proprietary information in your abstract.

Research awards may enter zero for "Estimated number of people to be served as a result of the award of this grant."

d. Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

3. Application Content

Successful applications will contain the following information:

a. Project Narrative Content

The Project Narrative is the most important part of the application, because it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

1. Significance of the Proposed Intervention

In this section, describe how the intervention is unique, innovative, and potentially addresses gaps in the adolescent health/TPP fields. Indicate how you will ensure that the intervention does not duplicate other programming that is already available to the population of focus. Tell us why your proposed project is likely to prevent unintended teen pregnancy, sexually transmitted infections (STIs), behavioral risk factors underlying teen pregnancy, or other associated risk factors. Describe how the project will add to the knowledge base. Identify your intervention by name and clearly and succinctly describe the who, what, when, where, why, and how of your intervention. Include the priority population that will receive the intervention. Indicate the setting where the intervention will take place. Describe the intervention, including, but not limited to a description of participant materials, the topics and themes covered by the intervention, the duration of the intervention, and how you will deliver the intervention to participants. Tell us who implements the intervention and what qualifications or training staff need to implement the intervention.

- If your intervention is a systems-level or community-level one, describe the boundaries of the system or community.
- If your intervention is technology-based, note any equipment end-users need to access the intervention.
- If your intervention is a major adaptation of a program identified as effective by TPPER, explain clearly what major adaptations you have made, how the core components have changed, and demonstrate that your intervention is essentially a new one.
- If anyone has rigorously evaluated your intervention before, and the results of previous studies did not identify evidence of effectiveness, explain why the significance of the intervention warrants additional rigorous impact evaluation of the intervention.

Describe your theory of change for the intervention. You may reference a logic model included in your appendices (Section D.3.c) to support your narrative; an optional sample template is available under the Related Documents tab on grants.gov for this opportunity. You should clearly indicate the outcome measures for your evaluation, including at least one sexual risk behavior. You may also examine non-sexual behavioral risk factors underlying teenage pregnancy (such as increased parent-child interactions, increased positive relationships with peers, improved mental health, reduced substance use, or other similar factors). If using such

measures, clearly demonstrate how the outcomes are related to preventing unintended teen pregnancy and address the needs of the community and population of focus. You should justify the significance of your intervention and why your intervention is well-suited to a rigorous evaluation. Your theory of change and logic model should be consistent with the intervention description.

Summarize all previous testing, research, and evaluation done on the intervention. Specify the type of evaluation(s) done such as formative evaluation, implementation evaluation, or pre-post tests, or other types. Describe the key findings on TPP-relevant outcomes (such as sexual behaviors, knowledge of contraception use, intentions to use contraception, etc.). Explain specifically how the prior research supports your theory of change. Indicate why the research shows that the intervention has promise and merit for reducing unintended teen pregnancy.

Summarize any research that shows the intervention is user-centered and therefore a good fit for the participants. Describe any data that shows previous participants liked the intervention, or that the community supports the intervention. Provide evidence that the intervention will have good uptake among the priority population. Include data that shows whether previous participants had a favorable experience, high levels of engagement, or satisfaction with the intervention. Describe any previous user testing to develop or refine the intervention and specify how you used past participant feedback to develop and refine the intervention.

Describe any resources or processes used during the development of the intervention to ensure that materials are medically accurate, age appropriate, complete, culturally and linguistically appropriate, trauma-informed, user-centered, and inclusive of all youth. Describe the status of the materials with respect to meeting the requirements of the OPA materials review process during the first year of the project. Include in your appendices any Memorandum of Agreement (MOA) from the developer/purveyor/copyright holder of the intervention indicating that you have permission to use and to make any changes to materials in response to the OPA materials review.

2. Impact Evaluation Design

Provide a thorough description of your impact evaluation design in your application; an optional sample template is available under the Related Documents tab on grants.gov for this opportunity. Propose the most robust design that is feasible for your intervention and setting and justify why that is the case. Where feasible, propose an evaluation design consistent with the study quality standards of the HHS TPP evidence review protocol, version 6.0 (https://tppevidencereview.youth.gov/ReviewProtocol.aspx). Your impact evaluation design should include the following:

a. Research Questions

State your proposed research questions. Indicate which questions are primary and which are secondary. Focus each question on a single outcome at a single time point.

Explain clearly how each research questions aligns with the intervention and its theory of change as described above (Section C.1.a.1.). You may reference material you included in the proposed

intervention section of your application (Section C.1.a.1.).

You should include at least one research question that assesses the intervention's impact on a sexual risk behavior (such as initiation of sexual activity, frequency of sex, number of sexual partners, contraceptive use, STIs, pregnancies, births, etc.).

You may propose additional research questions that address other behavioral risk factors underlying unintended teen pregnancy or other associated risk factors for unintended teen pregnancy (such as mental health, educational attainment, healthy relationships, intimate partner violence, substance use, etc.). The outcomes must align with your intervention's logic model. Provide supporting information that clearly links all proposed research questions and outcomes to the reduction of unintended teen pregnancy. Clearly demonstrate how the outcomes you are testing would address the needs of the community and population of focus.

Describe how answering these questions will improve programs, outcomes, and/or policies for youth.

b. Type of Study Proposed and Justification

Describe the type of study proposed. Appropriate studies are either RCTs or QEDs with comparison group (Section B.2.b). Indicate whether you would conduct an efficacy or effectiveness trial. Justify why the type of study proposed is the most robust design feasible for the intervention and setting for your project. Your evaluation should include a comparison group to meet OPA's standards of rigor.

c. Description of the Formation of Study Groups

Describe how you will form the study groups (i.e., intervention and comparison). Describe differences between your study groups, along with strategies to minimize potential contamination.

- For RCTs, clearly state the unit of random assignment and indicate that you have aligned it with the unit of analysis. Briefly describe the random assignment procedure, including whether you plan to use blocking/stratification and a justification for doing so.
- For QEDs, describe the method for formation of the comparison/counterfactual.

d. Comparison Experiences and Study Context

Describe any intervention or programming your team will provide to the individuals in the comparison group. Indicate any other TPP-relevant programming the comparison group members might receive in addition to programming provided by your project team (e.g., for example, business as usual programming provided by the study sites). Contrast the proposed comparison group experience to the experience of individuals receiving the intervention. Describe how the team will ensure that the experiences of both the intervention and comparison groups would be sufficiently different from each other.

Confirm that the study groups will have different levels of exposure to TPP content. Describe why the proposed programming for the comparison group will not affect contrast between the groups.

e. Data Collection Plan and Outcomes

Describe your plans for obtaining data for the study. Specify what data will you obtain, and clearly state how the data aligns with the outcomes for your research questions. Indicate the timing of data collection. Most projects collect baseline data, short-term follow-up data, and either intermediate or long-term follow-up data (Section A.2.b). Describe any systems that you will use to enter and store data. Justify why your data collection plan is likely to be successful.

If conducting surveys, describe the survey instrument(s) you will administer. Indicate how you will administer surveys to participants (e.g., by phone, in-person, web-based). Indicate whether the mode of data collection is the same for the intervention and comparison groups. Indicate the proposed timeline for participant recruitment, consent and assent, and data collection. Demonstrate that all proposed data collections will take place within the 5-year period of performance. Align this information with the project work plan in the appendix. If you propose using secondary or administrative data for your analysis, describe the secondary data source(s) that you would use. Indicate how and from whom you would obtain permission for obtaining the data. Verify that the timing of the data would align with the timing of your project. Describe the variables that align with your research questions and verify that outcomes would be available for both the intervention (treatment) and counterfactual (comparison or control) groups. Summarize your evaluator's relevant experience with the collection and analysis of the type(s) of data you propose for the study (you may reference information contained in your capacity section below; See Section C.1.a.6).

f. Human Subjects Protections, Data Privacy and Security

Identify the Institutional Review Board (IRB) you will use during the study, including the Federal-wide Assurance number and IRB registration number. Include a proposed timeline for acquiring the approval of the IRB for the proposed activities. Any award based on your application does not supersede the need for IRB review, approval, or determination of an exemption. **Do not** include in your application the package prepared for your IRB review.

Discuss your process for obtaining consent and assent from study participants. Describe the estimated rate of consent for study participants and provide a reasonable justification of the expected consent rate based on previous studies conducted by your team. Discuss the timing of the consent process relative to the formation of the study groups (for an RCT, this would be relative to the timing of random assignment). Estimate the number or proportion of sample members who will provide consent, relative to the number of individuals recruited for potential participation. Provide evidence that the evaluation team has achieved a similar consent rate in a similar evaluation. If consent must happen after random assignment, describe how your team will keep the consent process blind to treatment status.

Describe how you will securely store any sensitive data collected from study participants.

g. Statistical Power, and Minimal Detectable Effect (MDE) Size

Describe how you plan to estimate the causal impact of the intervention. Show the minimum detectable effect (MDE) size needed for an impact and explain how you calculated the MDE.

Estimate the statistical power for the study and demonstrate that the power is consistent with study design. Describe the statistical power analysis used to arrive at the sample size. Calculate a Minimum Detectable Effect (MDE) that has an 80% chance of being statistically significant at a specific alpha level, for each outcome. Describe the outcomes and assumptions used in the statistical power calculations. Provide sufficient justification as to why the study will find an effect larger than the MDE calculated.

If you plan to conduct analyses of subgroups, present additional statistical power analyses to estimate those MDEs.

h. Sample Size, Recruitment, and Retention

State your proposed sample size, based on your Power calculations above. Explain the plan to recruit participants for the study and justify that your team can recruit the full sample within the period of performance at the proposed implementation sites or communities. Indicate how you will maximize the participation of individuals who are part of the evaluation sample – both treatment and comparison groups. Indicate whether the IRB is likely to approve any proposed incentives. Describe how the incentives would successfully improve participation. Describe and justify the expected survey response rates. Describe any barriers and challenges to participant recruitment and retention you expect to encounter and how you plan to address them.

We expect most evaluation designs to be sufficiently well-powered to detect impacts for the primary research question(s) (80 percent chance of being statistically significant at the $p<.05$ level). We encourage applicants with anticipated small sample sizes (e.g., projects in juvenile justice or foster care settings) to propose Bayesian analyses to supplement their analysis or to propose other approaches suited to small samples with a and justification for the approach. Examples of relevant evaluation technical assistance resources are in Section I.5.

Describe how you will maintain sufficient participant contact information that will ensure the evaluation team can maintain contact with participants throughout the entire study.

i. Readiness and Feasibility

Describe the readiness of all study materials, processes, and procedures. The materials should include participant materials delivered to either the treatment or comparison groups, study instruments, and Institutional Review Board (IRB) application materials, etc. You should reference the timelines in your project's work plan (Section D.3.c). Demonstrate that your project is likely to be ready for full implementation by the end of the 12-month planning period.

j. Biases, Limitations, Threats to Validity, and Independence of Evaluation

Explain how you will conduct the evaluation through a credible and neutral process, including evaluation staff who do not have perceived or actual conflict of interest and can remain independent from the intervention. Tell us how you will ensure that the evaluation and the implementation of the intervention are independent from each other.

Explain any other limitations and biases, and how you plan to address them.

k. Supplemental analyses

Describe and justify any supplemental or exploratory analyses you plan to complete in addition to the impact and implementation evaluation. The additional analyses may include cost studies, qualitative data analyses, core components analyses, etc. Include any exploratory analyses proposed to uncover relationships between variables.

You may use the Treatment on Treated (TOT) Framework for supplemental analyses (ACF OPRE, 2016). If you do, demonstrate that you can complete the supplemental analyses by the end of the project and with the proposed staffing level without compromising the quality of the impact evaluation.

3. Implementation Evaluation and Project Improvement

Describe how you will monitor the implementation of the intervention throughout the study. Indicate the criteria that you will use to assess whether your intervention's implementation occurred as you intended. Indicate how will you measure the dosage (the amount of the intervention received by participants). Describe what fidelity adherence to the key project activities looks like and how you will monitor this during the study. Tell us how you will assess overall quality of implementation. You may use the TPP performance measures (Section I.6) as a basis for your dosage, fidelity adherence, and quality metrics. Indicate any other implementation metrics that you intend to track.

Tell us how you will collect and assess participant engagement. Indicate how will you monitor the context within which the study takes place and how you would ensure that your project does not duplicate other programming already offered within proposed sites or communities. Include any benchmarks that will you set for the implementation measures to ensure successful implementation of the intervention. Describe how will you use the implementation data to assess and improve the project.

Describe how you will monitor the experience of the comparison group throughout the study, including programming that comparison group members may receive outside the study. Indicate what data your team will use, and how often you will collect and assess that data.

Describe the process for monitoring the quality of the evaluation as it is occurring. Indicate what data you will use in the monitoring process, such as sample intake, response rates at baseline and follow-up, and intervention participation rates, etc. Indicate who would collect, monitor, and review the implementation data, how often you would review the data, and to describe how you

might use the data to make project improvements.

Describe how you will obtain, review, and use feedback from the intervention participants, end users, and other key community members, on the project throughout the period of performance.

Describe how any state and local policies at your sites may affect data collection and your plans to address any challenges, particularly in collecting the uniform TPP performance measures.

4. Organizational Capability, Partnerships, and Staffing

Describe your organization's capability to successfully manage and implement the proposed rigorous evaluation project. You should describe the structure of your organization (or the division of a larger agency which will have responsibility for this project), the nature and scope of its work, and the relevant capabilities it possesses. Describe the relevant capabilities of your organization not included elsewhere in the project narrative. Include and refer to your organizational chart in your appendices (See Section D.3.c).

Name all the organizations that you plan work with on the project. Indicate the roles and responsibilities of each organization on the project. The roles may include serving as study sites, recruiting study participants, implementing the intervention, or collecting data, etc. Describe clearly how each organization will contribute to achieving the project's objectives and outcomes. You should include supporting documentation for the partnerships (MOAs or LOCs) as described in Section D.3.c. For any proposed partnerships where an MOA will not be available when you submit your application, describe the timeline for securing an MOAs.

Identify the key personnel for the project, describe their role on the project, and include their organization of affiliation. Key personnel should include at minimum the Principal Investigator/Project Director (PI/PD) and Lead Evaluator for the project. Identify any additional project personnel whose contributions are essential to the project. Summarize the relevant skills, experience, and training for each key personnel position that demonstrates the person selected is well-suited to their role on the project.

Describe the PI/PD's relevant experience in overseeing, leading, and implementing projects of similar size and scope, with similar populations or settings, and using similar evaluation designs as that proposed.

Describe the Lead Evaluator's previous experience or training in conducting impact evaluations with a design similar to the design proposed; conducting implementation evaluations or process studies; working with similar interventions and populations; maintaining high sample retention and response rates; and managing and analyzing data. Show clearly that the Lead Evaluator has previous success using the methods proposed for this study and has familiarity with any administrative datasets proposed for use in the study. You may refer to the CVs/resumes/biosketches in the Appendices (Section D.3.c).

Explain why the proposed evaluation team has the capability to successfully execute the evaluation design. Explain why the staffing of the evaluation team is sufficient to successfully

complete all aspects of the study, including management, oversight, evaluation monitoring, data collection, data preparation, data analysis, and report writing. Provide evidence from previous evaluations that demonstrates successful recruitment, engagement, and retention of the participants throughout the study. Describe the evaluation team's experience disseminating evaluation findings and lessons learned in peer-reviewed publications, presentations at professional meetings, and briefings with key partners.

Describe who will be responsible for implementing the intervention and justify that the intervention team can deliver the intervention with high quality. Include any relevant, prior experience the implementation team has working with the priority population, within the proposed setting, and with the intervention (or similar interventions). Identify the team members or partner organizations responsible for implementing the intervention. Describe the successful results the intervention team has implementing interventions like the proposed project; successful results might include, for example, interventions conducted with high levels of participant engagement, attendance, participant satisfaction, or high quality. Support the information you provide with CVs/resumes/biosketches or position descriptions within your appendices.

Indicate any additional team members or partnering organizations that will recruit participants. Describe their ability to recruit a sample of the priority population large enough to meet the sample size estimates indicated earlier within your evaluation design.

Indicate whether any of your project team has previous experience collecting participant feedback and using the feedback to adjust programs.

Identify any plans to hire additional staff after an award, including a timeline for when you would hire them. You should include job descriptions in your appendices for any open positions.

Describe how you will assess and deliver any training and professional development for project staff relevant to their role, including training in delivering the intervention. Your plan should ensure that all staff responsible for implementing and evaluating the intervention are well-trained and prepared to successfully fulfill their roles and responsibilities. Indicate how you and your partners will hire and retain staff who are qualified, well-trained, and actively engaged in the project.

5. Project Management and Work Plan

Describe your project management approach with reference to the Work Plan table or chart submitted in your appendices (Section D.3.c). Specify who would have day-to-day responsibility for key tasks such as: leadership of the overall project, monitoring the evaluation, monitoring the quality of intervention implementation, preparation of reports; dissemination activities, and communications with other partners and HHS/OASH. Describe the approach that you will use to monitor and track progress on the project's tasks and objectives.

Clearly identify the individual who will serve as the PI/PD and that individual's qualifications, competing time commitments, and related ongoing projects. HHS/OASH expects that,

throughout the award period, the PI/PD will have substantial knowledge about all aspects of the project.

Include the time that your key project staff will spend on the project relative to their other commitments and justify that the proposed commitment to this project is sufficient for completion of all project goals, objectives, and activities, described in your work plan.

b. Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF-424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance). You must state the method you are selecting for your indirect cost rate. See Indirect Costs (Section D.3.b.1.o)) for further information. If you are providing in-kind contributions of any type or value, including costs otherwise covered by your indirect cost rate, you must identify those costs, and you should, as appropriate, include the value of the in-kind contribution as proposed cost-sharing (voluntary or required) (45 C.F.R. § 75.306).

Please be sure to carefully review Section D.7 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF-424A for the first year of the proposed project. For awards with an anticipated period of performance of one year or less, this will be the budget request for the entire project. Provide a budget justification, which includes explanatory text and line-item detail, for the entire first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years in an anticipated multi-year project, provide a summary narrative and line-item budget for each year beyond the first. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes.

Do not include costs beyond the first budget period in the object class budget in box 6 of the SF-424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget period.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. If you are proposing to provide services to clients,

you should describe how many clients you expect to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (if applicable) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying under this NOFO. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Sample Budget Table

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	$100,000	$25,000	$125,000

Subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items. For example, subrecipient travel should be included in the Contractual line item not in Travel. **Subrecipient/contract and consultant activities must be described in sufficient detail to describe accurately the project activities that each will conduct**.

1. Object Class Descriptions and Required Justifications

a. **Personnel Description**

Costs of staff salaries and wages, excluding benefits.

b. **Personnel Justification**

Clearly identify the PD/PI, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see D.7.2) Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. **Contractors and consultants should not be placed under this category**.

Sample Personnel Table

Position Title and Full Name	Percent Time	Annual Salary	Federally -funded Salary	Non-federal Salary	Total Project Salary

Project Director, John K. Doe	50%	$100,000	$50,000	$0	$50,000
Data Assistant, Susan R. Smith	10%	$30,000		$3,000	$3,000

c. **Fringe Benefits Description**

Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

d. **Fringe Benefits Justification**
Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

e. **Travel Description**
Costs of travel by staff of the applicant organization only. **Do not** include travel costs for subrecipients or contractors under this object class.

f. **Travel Justification**
For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors under this object class.

g. **Equipment Description**
Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.) See 45 C.F.R. § 75.2 for additional information.

h. **Equipment Justification**
For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the

equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

i. **Supplies Description**

Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than $5,000.

j. **Supplies Justification**
Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

k. **Contractual Description**

Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. **This line item is not for individual consultants.**

l. **Contractual Justification**

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 C.F.R. § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134 and currently set at $250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Whenever you intend to transfer a substantive part of the project effort to another entity (including non-employee individuals), you must provide a detailed budget and budget narrative for each subrecipient/contractor, by title/name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be transferred, the estimated costs, and the process for selecting the subrecipient/contractor.

m. **Other Description**

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as

tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

n. **Other Justification**

Provide computations, a narrative description, and a justification for each cost under this category.

o. **Indirect Costs Description**

Total amount of indirect costs. This category has one of two methods that you may select. You may only select one and must clearly identify that selection in your submitted budget.

- Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.
- Per 45 C.F.R. § 75.414 (f) Indirect (F&A) costs, "any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, … may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time."

The de minimis rate method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Indirect costs on Federal awards for training are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000 (45 C.F.R. § 75.414 (c)(1)(i)).

p. **Indirect Costs Justification**

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

q. **Program Income Description**

Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 C.F.R. § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 C.F.R. § 75.307 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

r. **Program Income Justification**

Describe and estimate the sources and amounts of program income that this project may generate, if funded. All program income generated as a result of awarded funds must be used within the scope of the approved project-related activities. Any program income earned by the recipient must be used under the addition/additive method unless otherwise specified in Section C.2. These funds should not be added to your budget, unless you are using the funds as cost sharing or matching, if applicable. This amount should be reflected in box 7 of the SF-424A.

s. Non-Federal Resources Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 C.F.R. § 75.306.

For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by period of performance for fully-funded awards, even if the justification by budget period, or by period of performance for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports.

For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Failure to meet a cost sharing or matching obligation that is part of the approved project budget on the NOA may result in the disallowance of federal funds.

If you are funded, you will be required to report cost sharing or matching funds on your quarterly Federal Financial Reports. You will not receive any preference,

priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

t. **Non-Federal Resources Justification**

You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by period of performance for fully-funded awards).

Unrecovered indirect costs may be included as part of your cost sharing or matching only with prior approval of the grants management officer. Your budget narrative must clearly state that it is your intent to include unrecovered indirect costs as part of your cost sharing or matching. You should include a copy of your negotiated cost rate to support the justification. Unrecovered indirect cost means the difference between the amount charged to the Federal award and the amount which could have been charged to the Federal award under your approved negotiated indirect cost rate. (See 45 C.F.R. § 75.306(c)).

If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review (Section C.4(k)).

2. **Plan for Recipient Oversight of Federal Award Funds**

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Grants and Acquisitions Management Division via the Payment Management System as well as timely and appropriate withdrawal of cash from the Payment Management System.

If your internal controls are available online, it is recommended that you provide the link as part of your plan in the budget narrative. We have also included supplementary

information in Section I.1, which contains questions applicants may find useful in considering their Recipient Plans for Oversight of Federal Funds.

c. Appendices

All items described in this section will count toward the total page limit of your application. You must submit them as **a single electronic file** uploaded to the Attachments section of your Grants.gov application.

1. Work Plan

Your work plan should reflect, and be consistent with, the project narrative and budget narrative, and must cover all years of the proposed project . However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your work plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. Activities/tasks should link to SMARTIE (specific, measurable, achievable, relevant, time-bounded, inclusive, and equitable) objectives, which then tie to overall goals and measurable outcomes (See the Resources in Section I.5 for more information about SMARTIE objectives). The work plan table should include tasks relevant to the evaluation and the implementation of the intervention. The work plan should include planning period activities (during the first year), all data collection activities, and allow 6-9 months at the end of the project for data analysis and reporting. The work plan should address all the expectations in Section A.2, such as developing program packages and dissemination plans. The work plan should be consistent with the project narrative.

2. Logic Model

Submit with its application a detailed logic model that describes the inputs, objectives, activities, outputs, and short- and long-term outcomes of the intervention being tested through the proposed project. All program objectives, activities, and anticipated outcomes shall be reflected in the logic model and demonstrate that the proposed project reflects a coherent approach. The logic model should visualize how the intervention's theory of change operates on participants to achieve the TPP-relevant outcomes.

3. Memoranda of Agreement (MOAs) and/or Letters of Commitment (LOCs)

If available at the time of submission, signed MOAs or signed LOCs may be submitted for each partner (or one signed MOA with all partners) and include specific roles, responsibilities, resources, and contributions of partner(s) to the project. Submit a signed MOA or LOC from the intervention developer/purveyor/copyright holder indicating that you may use the materials as described within the application in the project.

Signed LOCs must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the LOC. Fully-executed MOAs may be required within the first 30 days following the start of the project of any award made under this announcement.

MOAs and LOCs are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support, and letters of support will not be considered during the review.

4. Organizational Chart

Include an organizational chart that reflects the management structure for the project and demonstrates where the project resides within the greater organization.

5. Curriculum Vitae/Résumés/Biosketches for Key Project Personnel

Submit with your application curriculum vitae, résumés, or biosketches of the Project Director/Principal Investigator, Lead Evaluator, and all other Key Personnel. Key Personnel includes those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum Program Manager/Program Coordinator. You should use full names (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records. You should use the formatting common to those documents. (See https://grants.nih.gov/grants/forms/biosketch.htm for templates and sample biographical sketches.)

6. References Cited

Include your references cited in your project narrative as an appendix. Include citations for all evidence of evaluations conducted on the proposed intervention to date. You may use any standard format that you choose as long as it will clearly lead the reader to your source of the information or data.

4. Unique Entity Identifier and System for Award Management (SAM)

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You will find instructions on the Grants.Gov web site as part of the organization registration process at https://www.grants.gov/web/grants/applicants/organization-registration.html.

To register your organization, you will need a unique entity identifier (UEI). On April 4, 2022, the federal government completed its transition to the twelve-digit UEI(SAM) number as the required UEI for registration in SAM.gov.

You may begin the registration process, including receiving your UEI(SAM) at https://sam.gov/content/entity-registration. An Entity Registration Checklist is available at https://www.fsd.gov/gsafsd_sp/sys_attachment.do?sys_id=d6d6b5f31b120dd0cc45ea04bc4bcb81. You may register in SAM as either an entity applying for Federal Assistance Awards Only (e.g., grants and cooperative agreements) or All Awards (including procurement awards).

The Entity Registration Checklist contains a list of representations and certifications that must be certified by the organization as part of the SAM registration process annually. This list is reproduced in Section I.4. In accordance with the federal government's efforts to reduce reporting burden for recipients, we have transitioned to the common certification and representation requirements within SAM and no longer require SF-424B. By submitting your application to this NOFO, your authorized representative also certifies to these representations and certifications by signing Box 21 of SF-424A

Whether you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to SAM.gov. For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/gsafsd_sp?id=kb_article_view&sysparm_article=KB0016652&sys_kb_id=f228607a1b2e8d54937fa64ce54bcbdb&spa=1.

You should allow a minimum of five days to complete an initial SAM registration. Allow up to 10 business days after you submit your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.

You must renew your SAM registration each year. Organizations registered to apply for Federal awards through http://www.grants.gov will need to renew their registration in SAM. If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, your organization's legal name and physical address must be included on a Notice of Award as it appears in SAM registration.

For instructions on updating information in your SAM registration see https://www.fsd.gov/sys_attachment.do?sys_id=d08b64ab1b4434109ac5ddb6bc4bcbbc.

It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 C.F.R. § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

- May determine that you are not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a UEI number at the time you, the recipient, make a sub-award to them.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated below.** Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your submission.

If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with https://grants.gov. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

a. Application Deadline

May 17, 2023
Your application is due by 6:00 PM Eastern Time

You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, Grants and Acquisitions Management (GAM) Division, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS). To obtain an exemption, you must request one via email from GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline.

If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's UEI number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (e.g., GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to

OASH_Grants@hhs.gov.

Failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will not be grounds for receiving an exemption to the electronic submission requirement.

GAM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section D.8 ("Other Submission Requirements") for information on application submission mechanisms.

To ensure adequate time to submit your application successfully, OASH recommends that you register as early as possible in Grants.gov because the registration process can take up to one month. You must register an authorizing official for your organization. OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to https://grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

b. Technical Assistance

We will provide a technical assistance webinar for potential applicants on March 20, 2023, at 3:00 PM Eastern. Login details will be posted at https://opa.hhs.gov/.

We recommend you review the entire NOFO promptly, so that you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this NOFO in Grants.gov, so that you will receive any amendments, question and answer documents, or other updates.

6. Intergovernmental Review

This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented by 45 C.F.R. part 100.

7. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 C.F.R. part 75 "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards," Subpart E—Cost Principles. These

requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 C.F.R. § 75.414. See Section D.3.b Budget Narrative for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at https://rates.psc.gov/fms/dca/map1.html.

a. Pre-Award Costs

Pre-award costs are NOT allowed.

Pre-award costs (per 45 C.F.R. § 75.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work.

b. Salary Rate Limitation

Each year's appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2023, the Executive Level II salary is $212,100. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award. An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's *actual* base full-time salary: $350,000 50% of time devoted to project, i.e., 0.5 FTE	
Direct salary ($350,000 x 0.5)	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full-time salary *adjusted* to Executive Level II: $212,100 with 50% of time devoted to the project	
Direct salary ($212,100 x 0.5)	$106,050

Fringe (25% of salary)	$26,512.50
Total amount allowed	$132,562.50

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

a. **Electronic Submission**

HHS/OASHrequires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at https://grants.gov.
Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. **We will not accept Microsoft Excel files.**

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed files in the application will not be forwarded to the independent merit review panel for consideration.

We strongly recommend that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission, you may prevent any unintentional formatting that might occur with submission of an editable document. Although Grants.gov allows you to attach any file format as part of your application, we restrict this practice and only accept the file formats identified above for compatibility with our other systems. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files. Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

b. **Important grants.gov Information**

You may access the electronic application for this program on https://grants.gov. You must search the downloadable application page by the Opportunity Number or Assistance Listing (formerly CFDA) number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-grants.html . These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Section G.3 for contact information.

See Section D.4 for requirements related to UEI numbers and SAM registration.

c. Program-Specific Requirements

There are no program specific requirements.

E. APPLICATION REVIEW INFORMATION

1. Criteria

Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria.

a. Significance of the Proposed Intervention (30 points)

- The application demonstrates the intervention's significance to the TPP/adolescent health field and innovation in addressing gaps for reducing unintended teen pregnancy, and the behavioral risk factors or other associated risk factors underlying teen pregnancy. The intervention does this through its delivery mechanism, duration, the focus population, the setting, the topics, and themes covered. Behavioral risk factors may include sexual activity, number of sexual partners, contraceptive use, sexually transmitted infections (STIs), etc. Other risk factors may include mental health, educational attainment, healthy relationships, intimate partner violence, substance use, etc.
- The articulated theory of change is reasonable, consistent with the intervention, and supported by compelling preliminary research that demonstrates the intervention is likely

to reduce unintended teen pregnancy, sexually transmitted infections (STIs), behavioral risk factors underlying teen pregnancy, or other associated risk factors.

- The evidence of end-user feedback and other information demonstrate that the intervention is well-suited for the proposed implementation. The project includes processes to ensure that the materials are medically accurate, age-appropriate, complete, culturally and linguistically appropriate, trauma-informed, user-centered, and inclusive of all youth. Previous studies indicate that the program was well-liked by participants.

b. Evaluation Design: Research Question and Study Design (15 points)

- The proposed research questions are well-reasoned, focused, well-aligned with the intervention's theory of change, and clearly address the reduction of unintended teen pregnancy, behavioral risk factors underlying unintended teen pregnancy, or other associated risk factors for unintended teen pregnancy. At least one research question assesses the intervention's impact on a sexual risk behavior associated with unintended teen pregnancy. Behavioral risk factors may include sexual activity, number of sexual partners, contraceptive use, sexually transmitted infections (STIs), etc. Other risk factors may include mental health, educational attainment, healthy relationships, intimate partner violence, substance use, etc.
- The applicant proposes an appropriate type of impact study with comparison group (either a Randomized Control Trial or a Quasi-Experimental Design) and justifies why the evaluation design proposed is the most rigorous feasible for the setting and intervention and is realistic a 5-year project.

c. Evaluation Design: Methodology (25 points)

- The applicant adequately justifies that assignment of participants to the treatment and comparison groups i will ensure baseline equivalence and proper contrast between the groups for the research question.
- The estimated statistical power for the study is consistent with study design to ultimately demonstrate the effectiveness of the intervention. The statistical power analysis used to arrive at the sample size includes the Minimum Detectable Effect (MDE) that has an 80% chance of being statistically significant at a specific alpha level, for each outcome. The application considers the outcomes and assumptions used in the statistical power calculations, including presence in the area of similar interventions and available target sample, the description is consistent with the proposal as a whole.
- The applicant indicates a feasible sample size for the study, consistent with the proposed power calculations, and a clear and realistic rationale for how the team could recruit and retain enough participants to reach the proposed sample size, while accounting for attrition. The applicant describes an effective approach to maximizing and maintaining the participation of individuals within the evaluation sample. The applicant justifies its expected survey response rates, discusses potential challenges to recruitment and retention, and proposes a sound approach to addressing them.
- The application includes a sound, feasible data collection plan that will succeed. The applicant specifies the source(s) of data they will use in the study and clearly demonstrates that the evaluation team has the relevant expertise with the data collection methods and sources proposed. The applicant describes outcomes in the data collection plan that align with the intervention's logic model, theory of change, and the proposed

research questions. The timelines for data collection are realistic for a 5-year project and are consistent with the project work plan.

- The extent to which the applicant clearly describes how they would conduct the study in a credible and neutral manner, including at a minimum, evaluation staff who do not have perceived or actual conflict of interest and can remain independent of the intervention. The extent to which the applicant clearly discusses study limitations and biases and presents a sound plan that is likely to address them.
- The applicant describes a sound and feasible process for protecting human subjects that is likely to obtain participant consent and assent and secure sensitive data with appropriate IRB oversight and approval. The applicant described a feasible timeline for obtaining IRB approval(s) with the identified the IRB(s) by name.

d. Implementation of the Intervention and Project Improvement (15 points)

- The proposed implementation plan is a clear and feasible approach for ensuring a high-quality implementation of the intervention throughout the study with adequate monitoring of dosage, fidelity, overall quality of implementation, participant engagement and satisfaction, sample intake, participation, and response rates. The plan describes how and when the applicant will collect and use data to assess and improve the project. The applicant describes a sound plan to monitor the context of the evaluation and the experience of the comparison group.
- The applicant clearly describes the role(s) of all proposed partners and provides a compelling rationale for choosing its partners. The strength of proposed partnerships overall is adequate to support project activities. Signed Memoranda of Agreement (MOAs) or Letters of Commitment (LOCs) within the appendices support the partnership demonstrate the level of commitment needed for the project to be successful.
- The applicant describes a feasible and equitable strategy for engaging end-users of the intervention in the ongoing planning and implementation of the entire project. The proposed strategies are likely to obtain significant input from members of the priority population in the implementation of the intervention, conduct of the evaluation, and dissemination of findings.
- The applicant organization, its partners, and staff including the lead evaluator, PI/PD, and key project staff, demonstrate sufficient capacity and capability to successfully complete the proposed project within 5 years. The applicant demonstrates capacity i through sufficient staffing assignments; staff with the necessary and relevant experience, qualifications, and training; previous experience managing rigorous evaluation studies similar in size and scope to the proposed project; and examples of successful rigorous evaluation studies in similar settings and contexts and with similar populations as the proposed study.
- The project team demonstrates past success in project planning and improvement for the recruitment and retention of the intended population, collecting data, analyzing data, reporting on evaluation studies, and engaging community members and end-users.
- The application clearly identifies the team members/organizations responsible for implementing the intervention, and they demonstrate prior experience working with the priority population and within the proposed implementation setting. The intervention team has a clear track record of implementing interventions similar to the proposed

project. Resumes/biosketches/CVs/position descriptions within the appendices clearly support the information within the narrative.

e. Project Management and Work Plan (10 points)

- The application describes a reasonable plan for appropriate oversight for the project to manage the implementation of the intervention and its evaluation including monitoring each activity and collaboration partner. The application clearly demonstrates that the PI/PD and other key personnel have sufficient availability to ensure adequate oversight. An organization chart within the appendices supports the information in the narrative.
- The application provides a reasonable and feasible timeline for successfully completing the project within 5 years, realistically accounts for the readiness of project materials and staffing levels, and includes a planning period of up to 12 months. The project timeline includes all study implementation activities and is consistent with the evaluation design. Data collection concludes at least 6 months from the end of the project to allow sufficient time for analysis and report writing.
- The work plan is consistent with the project narrative, includes plans for disseminating project findings and lessons learned, and includes plans to document the intervention with sufficient detail so that others may replicate it after end of the award.

f. Budget (5 points)

- The budget and budget narrative are detailed, reasonable, realistic, adequate, cost-efficient, and aligned with the technical approach and work plan.

2. Review and Selection Process

An independent review panel will evaluate applications that are not disqualified and meet the responsiveness criteria (Section C.3). These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and rate the applications, focusing their comments and ratings on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Deputy Assistant Secretary for Population Affairs will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. No award decision is final until a Notice of Award is issued by the Grants Management Officer.

In providing these recommendations, the Deputy Assistant Secretary for Population Affairs will take into consideration the following additional factors(s):

- Equitable geographic distribution
- Non-duplication of or overlap with existing interventions
- Diversity of any of the following: interventions, populations of focus, settings, and delivery mechanisms or location
- Technical components in the evaluation design or intervention resulting in an unacceptable risk of meeting proposed project objectives.

3. Review of Risk Posed by Applicant

GAM will evaluate, in accordance with 45 C.F.R. § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. We will use a risk-based approach and may consider any items such as the following*:*

a. Your financial stability;

b. Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;

c. History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

d. Reports and findings from audits performed; and

e. Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 C.F.R. § 75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must “demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics.” 45 C.F.R. § 75.205(a)(2);

see also 45 C.F.R. §75.212 for additional information.

4. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including the level of funding if an award is made, are final and you may not appeal.

OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B "Federal Award Information," as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later period of performance start date.

F. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

We do not release information about individual applications during the review process. If you would like to track your application, please see instructions at https://www.grants.gov/web/grants/applicants/track-my-application.html.

The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer within GAM. If you are successful, you will receive this document via a system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. We do not customarily release application scores.

You may receive a letter indicating that your application was "approved but unfunded." This does not mean you will receive an award or funding. Applications designated "approved but unfunded" are typically kept active for up to one year. During that time, the program office may

consider an application with this status for award under this NOFO should funds become available. The status "approved but unfunded" does not guarantee that we will fund your project. We will not transfer an "approved but unfunded" application for consideration under a new NOFO. You would need to resubmit your application, with any updated material, for consideration under that new NOFO.

2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 C.F.R. part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf. Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 C.F.R. parts 74 and 92 which have been superseded by 45 C.F.R. part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 C.F.R. § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

The termination provisions in 2 CFR §§ 200.340(a)(1)-(4) are the termination provisions that are applicable to awards issued under this NOFO. No additional termination provisions apply unless otherwise noted under Section F.3 Program Specific Terms and Conditions.

3. Program Specific Terms and Conditions

a. Performance Measures

If you are successful and receive a Notice of Award (NOA), you must collect uniform performance measures and report to us on a semi-annual basis. Section I.6 includes a list of the draft measures used within the TPP 2020 cohort (OMB #0990-0348 Expiration Date: August 2023, pending renewal). We will provide final measures for the TPP 2023 cohort during the first 6 months of the project. You would be required to obtain and document any necessary permissions to collect these data. Documentation may include formal agreements with partners (MOAs), consent forms from parent/guardians, copies of school district approvals, citation to state law, etc. to collect these data. You may be required to provide the supporting documentation for review, on request. You would have the responsibility to ensure you have appropriate permissions to collect all required performance measure data prior to collecting the data. There are no exceptions or waivers for this requirement.

While implementing and evaluating some non-curricular approaches, such as technological innovations, systems-level, and community-level approaches, you may find that some OPA measures or constructs (e.g., dosage, fidelity, and quality) are not relevant to your intervention. If you identify a need to change a measure, you would need prior approval from OPA to use alternate or proxy measures for dosage, fidelity, or quality. You would be required to develop the measures that future implementors of the intervention could use to monitor fidelity, quality, and dosage, and include those in the final program package (Section A.2.h.).

b. Paperwork Reduction Act Clearance Packages

If you are successful and receive a NOA, any collection of information you conduct as defined in 5 C.F.R. §1320.3(c) may require OMB clearance under the Paperwork Reduction Act if it is a requirement of your award to collect that information. You would be responsible for preparing the clearance package necessary to obtain Paperwork Reduction Act clearance and submitting it to the project officer. The project officer will assist in the submission of the package to OMB and notify you when the approval has been received or request additional information.

4. Closeout of Award

Upon expiration of your period of performance, you must submit within 120 days all necessary documentation to closeout your award. If we do not receive acceptable final performance, financial, and/or property reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the PD/PI, we must complete a unilateral closeout with the information available to us. (See F.16 Reporting below for closeout reporting requirements.)

If you do not submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). As a result, we may also determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

5. Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State, or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

6. Non-Discrimination Requirements

Should you successfully compete for an award, as a recipient of federal financial assistance (FFA) from HHS you will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/forproviders/provider-obligations/index.html and https://www.hhs.gov/civil-rights/forindividuals/nondiscrimination/index.html.

- For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals. See https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on the specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS-funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf, provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. For further guidance on providing culturally and linguistically appropriate services, you should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

7. Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

8. Acknowledgement of Funding

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

> This [project/publication/program/website, etc.] was supported by [Award Number] issued by the Office of the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by [PROGRAM OFFICE].

Recipients must also include a disclaimer stating the following

> The contents are solely the responsibility of the author(s) and do not necessarily represent the official views of, nor an endorsement by, [PROGRAM OFFICE], OASH, HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

9. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 C.F.R. § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 C.F.R. § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Trafficking in Persons

Awards issued under this NOFO are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104) (See https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm).

11. Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/.

12. Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 C.F.R. § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

13. Health Information Technology (IT) Interoperability

Health information technology is defined in Section 3000 of the Public Health Service Act (42 U.S.C. § 300jj). HHS has substantially adopted and codified that definition at 45 C.F.R. § 170.102. The regulation defines health information technology as hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

If you receive an award under this NOFO that involves:

1.
    1.
        1. implementing, acquiring, or upgrading health IT for activities, you are required to utilize health IT that meets standards and implementation specifications adopted in 45 CFR Part 170, Subpart B, if such standards and implementation specifications can support the activity.
        2. implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Section 4101, 4102, and 4201 of the HITECH Act , you are required to utilize health IT certified under the Office of the HHS Office of the National Coordinator for Health Information technology (ONC) Health IT Certification Program, if certified technology can support the activity. See https://www.healthit.gov/topic/certification-ehrs/certification-health-it.

If standards and implementation specifications adopted in 45 CFR Part 170, Subpart B cannot support the activity, recipients and subrecipients are encouraged to utilize health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at https://www.healthit.gov/isa/.

14. Prohibition on certain telecommunications and video surveillance services or equipment.

As described in 2 C.F.R. 200.216, recipients and subrecipients are prohibited from obligating or spending grant funds (to include direct and indirect expenditures as well as cost share and program) to:

a. Procure or obtain;
b. Extend or renew a contract to procure or obtain; or
c. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by

Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

15. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. Additional information is available at https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Recipients that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to https://www.hhs.gov/about-research-participation.

OASH may require, as part of any award, the submission of all IRB approvals within 5 days of the IRB granting the approval and before any work requiring IRB approval begins.

16. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at https://ori.hhs.gov/assurance-

program.

17. Reporting

a. Performance Project Reports (PPR)

You must submit periodic performance project reports on a semi-annual basis. Your performance reports must address content required by 45 C.F.R. § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov).

You will also be required to submit a final performance report covering the entire period of performance 120 after the end of the period of performance. The awarding program office may provide additional guidance on the content of the progress report. You must submit the final report by upload to our grants management system (GrantSolutions.gov).

b. Performance Measures

We assess performance relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved work plan and other supporting documents.

At the end of each reporting period, you should be able to describe the performance in terms of:

- total number of partners
- total number of staff trained
- reach (the number of participants receiving the intervention)
- dosage (the percentage of the intervention participants received
- fidelity to the core components of the intervention
- overall quality of implementation

You must collect uniform performance measures and report to us on a semi-annual basis as described in Section F.3.a. Section I.6 includes a list of the draft measures used within the TPP 2020 cohort (OMB #0990-0348 Expiration Date: August 2023, pending renewal). We will provide final measures to recipients during the first 6 months of the project. You would be required to obtain and document any necessary permissions to collect these data. Documentation may include formal agreements with partners (MOAs), consent forms from parent/guardians, copies of school district approvals, citation to state law, etc. to collect these data. You may be required to provide the supporting documentation for review, on request. You would have the responsibility to ensure you have appropriate permissions to collect all required performance measure data prior to collecting the data. There are no exceptions or waivers for this requirement.

While implementing and evaluating some non-curricular approaches, such as technological innovations, systems-level, and community-level approaches, you may find that some OPA measures or constructs (e.g., such as dosage, fidelity, and quality) are not relevant to your intervention. If you identify a need to change a measure, you would need prior approval from OPA to use alternate or proxy measures for dosage, fidelity, and/or quality. You would be

required to develop the measures that future implementors of the intervention could use to monitor fidelity, quality, and dosage, and include those in their final program package (Section A.2.h.).

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire period of performance 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (https://pms.psc.gov).

Once submitted and accepted, your financial reports will be available in GrantSolutions, which is our grant management system.

d. Audits

If your organization expends $750,000 or greater in federal funds, it must undergo an independent audit in accordance with 45 C.F.R. 75, subpart F.

e. Non-competing Continuation Applications and Awards

Each year of the approved period of performance, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Progress is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the approved work plan and other supporting documents.

For the optional competitive additional year of funding for transition to sustainability, application guidance and review criteria will be provided during the third year of the project.

Failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

f. **FFATA and FSRS Reporting**

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (https://www.FSRS.gov) for all sub-awards and sub-contracts issued for $30,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

g. **Reporting of Matters Relating to Recipient Integrity and Performance**

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 C.F.R. part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 C.F.R. part 75.

h. **Other Required Notifications**

Before you enter into a covered transaction at the primary tier, in accordance with 2 C.F.R. § 180.335, you as the participant must notify OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 C.F.R. § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 C.F.R. § 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 C.F.R. § 180.350, you must give immediate written notice to OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 C.F.R. § 180.335; or
- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 C.F.R. § 180.335.

G. CONTACTS

1. Administrative and Budgetary Requirements

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Duane Barlow

OASH Grants and Acquisitions Management
1101 Wootton Parkway, Plaza Level
Rockville, MD 20852
Phone: 240-453-8822
Email: duane.barlow@hhs.gov

2. Program Requirements

For information on program requirements, please contact the program office representative listed below.

Tara Rice
Office of Population Affairs, 1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Phone: 240-453-8123
Email: tara.rice@hhs.gov

3. Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: https://www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

H. OTHER INFORMATION

1. Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for periods shorter than indicated. Only the grants officer can bind the Federal government to the expenditure of funds.

If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration.

2. Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.

Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.

Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application**.

Work Plan
Logic Model
Memoranda of Agreement (MOAs) and/or Letters of Commitment (LOCs)
Organizational Chart
Curriculum Vitae/Résumés/Biosketches for Key Project Personnel
References Cited

I. SUPPLEMENTARY MATERIALS

1. Acronyms

FAPIIS	Federal Awardee Performance and Integrity Information System
FFATA	Federal Financial Accountability and Transparency Act
FFR	Federal Financial Report (SF-425)
FSRS	FFATA Subaward Reporting System
GAM	Grants and Acquisitions Management Division
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPS	Grants Policy Statement
HHS	Department of Health and Human Services
HIV	HIV Human Immunodeficiency Virus
IRB	Institutional Review Board (IRB)
MDE	Minimum Detectable Effect
NOA	Notice of Award

NOFO Notice of Funding Opportunity

OASH Office of the Assistant Secretary for Health

OPA Office of Population Affairs

OMB Office of Management and Budget

PD/PI Project Director/Principal Investigator

QED Quasi-Experimental Designs

RCT Randomized control trials

RDD Regression discontinuity design

STI Sexually Transmitted Infections

SMARTIE Specific, Measurable, Achievable, Relevant, Time-bounded, Inclusive, and Equitable

TPP Teen Pregnancy Prevention

TPPER Teen Pregnancy Prevention Evidence Review

PHS Public Health Service

PPR Performance Project Report

SPOC State Single Point of Contact

2. Considerations in Recipient Plans for Oversight of Federal Funds

(See also Section D.3.b.2)

To the maximum extent possible, a recipient organization should segregate responsibilities for receipt and custody of cash and other assets; maintaining accounting records on the assets; and authorizing transactions. In the case of payroll activities, the organization, where possible, should segregate the timekeeping, payroll preparation, payroll approval, and payment functions.

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?
- Are specific officials designated to approve payrolls and other major transactions
- Does the time and accounting system track effort by cost objective?
- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?
- Do the procedures for cash receipts and disbursements include:
    - Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?

- Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
- All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?
- Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

3. Financial Assistance General Certifications and Representations

When your organization completes its registration (new or renewal) in SAM.gov, your organization has attested to the accuracy of the below. Note that HHS awards are currently subject to 45 C.F.R. part 75. Where applicable the parallel citation to 45 C.F.R. part 75 is supplied in brackets following the 2 C.F.R. part 200 citation.

a. Has the legal authority to apply for federal assistance and the institutional, managerial and financial capability to ensure proper planning, management, and completion of any financial assistance project covered by this Certifications and Representations document (See 2 C.F.R. § 200.113 Mandatory disclosures [45 C.F.R. § 75.113], 2 C.F.R. § 200.214 Suspension and debarment [45 C.F.R. § 75.213], OMB Guidance A- 129, "Policies for Federal Credit Programs and Non-Tax Receivables");

b. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives (See 2 C.F.R. § 200.302 Financial Management [45 C.F.R. § 75.302] and 2 C.F.R. § 200.303 Internal controls [45 C.F.R. § 75.303]);

c. Will disclose in writing any potential conflict of interest to the federal awarding agency or pass through entity in accordance with applicable federal awarding agency policy (See 2 C.F.R. § 200.112 Conflict of interest [45 C.F.R. § 75.112]);

d. Will comply with all limitations imposed by annual appropriation acts;

e. Will comply with the U.S. Constitution, all federal laws, and relevant Executive guidance in promoting the freedom of speech and religious liberty in the administration of federally-funded programs (See 2 C.F.R. § 200.300 Statutory and national policy requirements [45 C.F.R. § 75.300] and 2 C.F.R. § 200.303 Internal controls [45 C.F.R. § 75.303]);

f. Will comply with all applicable requirements of all other federal laws, executive

orders, regulations, and public policies governing financial assistance awards and any federal financial assistance project covered by this certification document, including but not limited to:

1. Trafficking Victims Protection Act (TVPA) of 2000, as amended, 22 U.S.C. § 7104(g);

2. Drug Free Workplace, 41 U.S.C. § 8103;

3. Protection from Reprisal of Disclosure of Certain Information, 41 U.S.C. § 4712;

4. National Environmental Policy Act of 1969, as amended, 42 U.S.C. § 4321 et seq;

5. Universal Identifier and System for Award Management, 2 C.F.R. part 2;

6. Reporting Subaward and Executive Compensation Information, 2 C.F.R. part 170;

7. OMB Guidelines to Agencies on Governmentwide Debarment and Suspension

(Non-procurement), 2 C.F.R. part 180;

8. Civil Actions for False Claims Act, 31 U.S.C. § 3730;

9. False Claims Act, 31 U.S.C. §3729, 18 U.S.C. §§ 287 and 1001;

10. Program Fraud and Civil Remedies Act, 31 U.S.C. § 3801 et seq;

11. Lobbying Disclosure Act of 1995, 2 U.S.C. § 1601 et seq;

12. Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d et seq;

13. Title VIII of the Civil Rights Act of 1968, 42 U.S.C. § 3601 et seq;

14. Title IX of the Education Amendments of 1972, as amended; 20 U.S.C. § 1681 et seq

15. Section 504 of the Rehabilitation Act of 1973, as amended; 29 U.S.C. § 794; and

16. Age Discrimination Act of 1975, as amended, 42 U. S.C. § 6101 et seq.

4. Glossary of Selected Terms and Definitions

Adaptations: changes to a program model's content, delivery, or core components.

Age appropriate: Ensures that topics, messages, and teaching methods are suitable to particular ages or age groups of children and adolescents, based on developing cognitive, emotional, and

behavioral capacity typical for the age or age group (Centers for Disease Control and Prevention, 2021) . An age-appropriate program addresses students' needs, interests, concerns, developmental and emotional maturity levels, experiences, and current knowledge and skill levels. Learning is relevant and applicable to students' daily lives and concepts and the intervention covers skills in a logical sequence (Centers for Disease Control and Prevention, 2019)

Core components: the key ingredients of an intervention or its implementation determined by the developer to be the key ingredients related to achieving the outcomes

Culturally and Linguistically appropriate: Assures that materials and language used are respectful of and responsive to the cultural and linguistic needs of the population served by an intervention. This includes being respectful and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs (Office of Minority Health, 2022) .

Dosage: measurement of the amount of an intervention received by a participant, such as by attendance records

Counterfactual: the comparison or control group(s) in the rigorous impact evaluation which provides a contrast to the treatment or intervention group; the comparison group within the study does not receive the treatment intervention.

Effectiveness Studies: Examine effectiveness of an intervention under routine practice or circumstances that would typically prevail in the target context. "Typical" circumstance means that implementation should be similar to what would occur outside of a study and that there is no more substantial developer or technical assistance support than in normal implementation.

Efficacy Studies: Allows for testing of an intervention under "ideal" circumstances. For example, these conditions may include more implementation support or more highly trained personnel than would be expected under routine practice, or in contexts that include a more homogenous sample of participants than is typical. Additionally, efficacy studies often including a higher level of support or developer involvement (if applicable) than would be the case under normal circumstances. Efficacy studies may choose to limit the investigation to a single population of interest.

Evidence-Based Program (EBP): an intervention identified as effective by the HHS Teen Pregnancy Prevention Evidence Review (TPPER). Such an intervention is not appropriate for rigorous evaluation under this NOFO unless substantial, major adaptations have been made that would change the core components and therefore the expected outcomes.

Fidelity: The degree to which an organization implements a program with adherence to its core components.

Formative Evaluation: Evaluation to test different elements of the intervention and its implementation. This can occur during the program development. Primary goal of the formative evaluation is to develop, test, and learn about the intervention before rigorous impact evaluation.

Health Equity: "The attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities" (Healthy People 2030).

Impact Evaluation: Evaluations designed to measure the impact of an intervention on a specific outcome. Impact evaluations generate evidence of efficacy or effectiveness of a fully developed intervention by providing estimates of the intervention's ability to achieve its intended outcomes. A rigorous impact evaluation is designed to test the intervention against a comparison condition (the counterfactual) in a credible and valid manner.

Implementation Evaluation: Research that seeks to assess the implementation of the intervention to answer questions about what was implemented and how and why an intervention works. Implementation factors include fidelity, dosage, quality, responsiveness, acceptability, feasibility, and context, among others.

Implementation Ready: To be implementation-ready, an intervention must have clearly defined program materials and components, necessary staff supports and training, specified guidelines for implementation, and tools for monitoring fidelity. Implementation-ready interventions include all the necessary components that will allow someone other than the original developer to implement the intervention effectively.

Independent Evaluator: the person(s) responsible for planning and conducting the evaluation. An independent evaluator has no pre-existing financial interest to the applicant (PI) or the intervention and has no conflicts of interest (such as but not limited to, being a relative of the proposed PI or having a financial stake in the intervention or its publisher/vendor)

Interrupted time series: This is a specific quasi experimental design approach used for evaluating causal effects of interventions. Under this approach researchers obtain multiple observations prior to the intervention to establish a baseline. Researchers obtain multiple observations after the intervention. The research demonstrates effects when the observations after the intervention deviate from expectations derived from baseline projections.

Intention to Treat (ITT): an analysis of the impact of the offer of the program upon the outcome(s) of interest. In other words, the treatment group contains all participants randomized

to receive the intervention, whether they actually participated in the programming/services.

Innovation: Novel or reimagined approaches, relationships, processes, products, programs, or services that lead to substantial improvements in addressing barriers to reducing teen pregnancy and STD transmission.

Intervention: Innovative or promising programs, models, components, curricula, products, approaches, and strategies evaluated by the recipient; what the treatment group of the impact study receives.

Medically Accurate: Verified or supported by the weight of research conducted in compliance with accepted scientific methods and published in peer-reviewed journals, where applicable, or comprising information that leading professional organizations and agencies with relevant expertise in the field recognize as accurate, objective, and complete.

Preliminary evidence: data from studies such as formative or implementation evaluation that suggest the innovation could have an impact on the specific behavioral outcomes of interest.

Propensity score matching: A statistical matching approach that is sometimes employed in quasi-experimental design studies for the purposes of developing a comparison group. This approach is based on a predicted probability of group membership (e.g., intervention vs. control) using measured characteristics of study units as predictors. The predicted probabilities obtained from logistic regression.

Project: All activities, including intervention implementation and evaluation, described in the application, and funded by the cooperative agreement.

Project Merit: Applicants may demonstrate project merit by showing that the intervention is needed by the population/community, the recipients liked the innovation, the innovation is a good fit for the population, and there is community support for the innovation.

Quasi-Experimental Design (QED): A design that forms a counterfactual group by means other than random assignment. Researchers use this approach for comparing observed changes in the treatment group with a comparison group (as a counterfactual representing an absence of intervention) to assess and estimate the impact of the program on participants. However, groups formed in these designs typically differ for reasons other than chance, and these differences may influence the impact estimate. There are different types of approaches used in quasi-experimental designs such as those using Propensity Score Matching (PSM), Regression Discontinuity, Interrupted Time Series (ITS) and others.

Randomized Control Trial (RCT): Experimental design studies assign program participants to two distinct groups (at random): the treatment group, which receives program services, and the

control group, which does not. The control group is the "counterfactual," representing the condition in which the program or intervention is absent. Random assignment ensures that the treatment and control groups are initially similar and do not differ on background characteristics or other factors. Random assignment, thus, creates an evaluation design where any observed differences between the two groups after the program intervention takes place can be attributed to the intervention with a high degree of confidence.

Random assignment: A process that uses randomly generated numbers or other approaches to assign study units to groups in ways that are unaffected by the characteristics of the study units. With random assignment, any differences between the groups at pre-test can be attributed only to chance. The use, or lack of use, of this process differentiates experimental designs from non-experimental designs.

Rigorous impact evaluation: Either a randomized control trial (RCT) or a quasi-experimental design (QED) with counterfactual condition; the most robust possible design that is feasible for the intervention

Regression discontinuity design (RDD): This is a specific quasi experimental design approach that is used for evaluating causal effects of interventions. Under this approach assignment to a treatment is determined at least partly by the value of an observed covariate lying on either side of a fixed threshold. The intervention and control group are formed using a well-defined cutoff score. The group below the cutoff score receives the intervention and the group above does not, or vice versa. For example, if students are selected for a program based on test scores, those just above the score and just below the score are expected to be very similar except for participation in the program and can be compared with each other to determine the program's impact.

Statistically significant: A result has statistical significance when it is very unlikely to have occurred given the null hypothesis (no relationship between two measured phenomena) or by chance. Typically, statistical significance is measured at the $p<.05$ level.

Systems Thinking: An approach to problem-solving that considers the overall system instead of focusing on specific parts of a system. This approach helps answer three basic questions: (1) how does the environment within which you work operate as a complex, dynamic system; (1) how will your strategy engage the system in order to have a highly leveraged impact; (3) and how will you test your assumptions and hypotheses about how your system works so that you can learn and adapt effectively?

Theory of Change: Theory of change is an ongoing process of reflection to explore change and how it happens, as well as what that means for a particulate intervention, in a particular context, sector, and/or group of people.

Treatment Group: The group affected by or receiving the intervention in a rigorous evaluation study.

Treatment on Treated (TOT): an analysis that assesses the impact of actual program participation upon the outcome(s) of interest

Trauma-informed: Refers to how a program, agency, organization, or community thinks about and responds to those who have experienced or may be at risk for experiencing trauma. It is an approach that: (1) realizes the widespread impact of trauma and potential paths for recovery; (2) recognizes the signs and symptoms of trauma in youth, families, staff, and others; (3) responds by fully integrating knowledge about trauma into policies, procedures, and practices; and (4) seeks to actively resist re-traumatization.

User-centered: An approach to project development that grounds its process in soliciting and understanding the perspectives and needs of the individuals, including youth and other stakeholders, for which interventions will ultimately be used.

Meaningful youth engagement: An inclusive, intentional, mutually respectful partnership between youth and adults whereby power is shared, respective contributions are valued, and young people's ideas, perspectives, skills, and strengths are integrated into the design and delivery of programs, strategies, policies, funding mechanisms and organizations that affect their lives and their communitie

5. Select Resources for Applicants

Bayesian Analysis

Office of Population Affairs. (February 2022). Tier 2 Phase II Webinar Bayesian Interpretation and Core Components Introduction. Evaluation Technical Assistance Webinar. Online at: https://rhntc.org/resources/tier-2-phase-ii-webinar-bayesian-interpretation-and-core-components-introduction, Accessed 10/31/2022.

Core Components

Office of Population Affairs (OPA) (September 2022). Core Components Analysis. Evaluation technical assistance webinar. Online at: https://rhntc.org/resources/core-components-analysis
Office of Population Affairs (OPA). (March 2020) Understanding How Components of an Intervention Can Influence Outcomes. Online at: https://opa.hhs.gov/sites/default/files/2020-07/corecomponentsbrief.pdf, Accessed 6/24/2022.

Fidelity Monitoring and Observations

Bradley, M.C., Borradaile, K., and Knab, J., (2020). Tip Sheet for Conducting Observations, Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, U.S.

Department of Health and Human Services. Online at: https://rhntc.org/sites/default/files/resources/opa_observation_tip_2020_04_17.pdf. Accessed 11/16/2022.
Chan, S., and Scher, L., (2020). Documenting Adaptations Tip Sheet, Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services. Online at: https://opa.hhs.gov/sites/default/files/2021-05/document-adaptations-tip-sheet-july-2020.pdf . Accessed 11/08/2022.
Office of Population Affairs (OPA). (July 2020) Fidelity Monitoring Tip Sheet. Online at: https://opa.hhs.gov/sites/default/files/2021-05/fidelity-monitoring-tip-sheet-july-2020.pdf, Accessed 6/24/2022

Impact Evaluation Resources

Office of Population Affairs (OPA). Evaluation Technical Assistance Webinars and Briefs. Online at: https://opa.hhs.gov/research-evaluation/evaluation-training-and-technical-assistance Accessed 11/18/2022.
Office of Population Affairs (OPA). Impact Evaluation Toolkit. Online at: https://rhntc.org/resources/impact-evaluation-toolkit. Accessed 10/31/2022.
Office of Adolescent Health (OAH). (September 2017) Estimating Program Effects on Program Participants. Online at: https://opa.hhs.gov/sites/default/files/2020-07/estimating-program-effects-on-program-participants-brief.pdf, Accessed 6/24/2022

Implementation Evaluation and Evaluation Planning Resources

Office of Population Affairs (OPA). Formative Evaluation Toolkit. Online at: https://rhntc.org/resources/formative-evaluation-toolkit . Accessed 10/31/2022.

Office of Population Affairs (OPA). (June 2022). Assessing Readiness for Rigorous Evaluation. Evaluation Technical Assistance webinar. Online at: https://rhntc.org/resources/assessing-readiness-rigorous-evaluation-webinar , Accessed 10/31/2022.

SMARTIE Work Plan

Centers for Disease Control and Prevention. National Breast and Cervical Cancer Early Detection Program. Writing Effective Objectives.
https://www.cdc.gov/cancer/nbccedp/pdf/smartie-objectives-508.pdf

6. TPP2020 Performance Measures (Draft- measures subject to change for the TPP2023 cohort)

OMB No. 0990-0468 Expiration Date: 8/31/2023

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.

During the reporting period, indicate the number of times each approach was used uniquely to communicate information to youth, caregivers, and the community about the TPP-funded grant project services and interventions available.
_____ Blogs/Online articles
_____ Social Media posts (such as Facebook, Twitter, Instagram, YouTube, etc.)

_____ # reactions
_____ # reshares
_____ # comments

_____ Peer Reviewed Publication (include box to require grantee to enter citation)

During the reporting period, indicate the number of times each approach was used uniquely to raise awareness within the community about optimal health and the issue of teen pregnancy prevention, sexually transmitted infections (STIs).
_____ Blogs/Online articles
_____ Social Media posts (such as Facebook, Twitter, YouTube, Instagram, etc.)

_____ # reactions
_____ # reshares
_____ # comments

_____ Peer Reviewed Publication (include box to require grantee to enter citation)

During the reporting period, where was information about the project presented? Write the number of times each presentation occurred.
_____National Conference/Event (include box to require grantee to enter citation)
_____Statewide Conference/Event (include box to require grantee to enter citation)
_____Local Meeting/Event

How many social media accounts (such as Facebook Twitter, Instagram, YouTube) does your organization use to share information about the TPP grant project? _____

Of these accounts, how many are specific to the TPP grant project? _____

How many followers does your TPP grant project specific social media account(s) have as of the end of the reporting period {DATE}? _____

Partners
Indicate the number of formal partners involved in implementing the grant-funded project during the reporting period. Formal partners are external organizations/agencies with whom the grantee has a written agreement (such as signed MOU, contract, or Letter of Commitment), and who are integral to the implementation and evaluation of the grant-funded project. Examples of partners may include program/intervention implementors (such as those organizations that provide sites, staffing, or both for TPP programming), partners who provide the supportive services to Tier 1 program participants, organizations that recruit TPP program participants, and/or organizations that provide ongoing strategic support to the project.

Total Number of Formal Partners (unduplicated, report as of the end of the 6-month reporting period) _____

Partner retention:

How many formal partners were involved with the project at the start of the grant year (Date)? _____

Of all the project's formal partners that were involved at the start of the grant year, how many were still involved in the project at the end of the reporting period? _____

Sustainability

During this reporting period, how much additional funding (that is, funding in addition to the TPP grant) have you secured to assist with project activities (i.e., program implementation, evaluation, communication, etc.)? _____

How many partners have firm plans in place to continue the project activities (program implementation, training, research, etc.) after the end of OPA grant funding? _____

How many different sources of funding do you have in place to support the grant project? _____

Training
Trainings would include professional development activities or technical assistance relevant to the implementation of project activities and provided to anyone responsible for implementing any aspect of the TPP grant project. Trainings may be for staff (from grantee and partner agencies) or community members (for example, youth trained as peer educators, community members serving on advisory groups.) Stakeholders who receive the TPP intervention as the end user or target population of the TPP intervention/program proven effective should be included under the reach section and not under training.

In the reporting period, how many trainings (professional development or technical assistance activities relevant to the project) have been provided through the TPP grant project to anyone affiliated with implementing the project? _____

In the reporting period, how many individuals affiliated with the TPP grant project (such as partner agencies, community members, stakeholders, project staff, youth who work with the project) have you or one of your partners trained via the grant funding (training includes any professional development or technical assistance relevant to the implementation of the project)?

_____

Questions at Section (Program or Intervention) Level
For each section (group or class receiving the Teen Pregnancy Prevention (TPP) promising intervention together), grantees report the following.
Name of the TPP Intervention being delivered:
Tier 2 grantees would report the TPP intervention that is being rigorously evaluated and would only report performance data for the participants in the intervention (treatment) arm of the rigorous study.

State/Territory where implemented:
Setting of Implementation: select one or more of the following that best describes where the majority of sessions in the section took place
In-school (Programs that take place primarily or exclusively during a school day on a school campus. This category may include public or private schools, traditional or alternative schools, of any grade level).
Clinic-based
Faith-based
Runaway and homeless youth (such as drop in shelter/centers, other)
Out-of-home (such as the child welfare system/foster care, group homes, residential centers. Juvenile justice should be counted separately below)
Juvenile justice (such as detention centers, residential centers –serving uniquely juvenile justice youth, camps)
other out-of-school time/community (programs that primarily take place outside of school hours, and may be located within a community organization not listed above or on a school campus before or after the school day)
Technology-based (includes programs that do not take place in a physical location, such as virtual programs, text messaging, apps, internet-based programs, etc.)

Urbanicity of Implementation Site: urban, rural, suburban

Reach and Demographics of TPP Participants

For each section (class or group) of TPP promising interventions implemented with youth, how many youth participated in your program for at least one activity in the reporting period? Report total numbers per section and numbers by each demographic category below:
Gender – Male, Female, Transgender, Does not identify, Not reported

Age – 10 or younger, 11, 12, 13, 14, 15, 16, 17, 18, 19, >19, Not reported

Grade – 6 or less, 7, 8, 9, 10, 11, 12, GED program, Technical/vocational training/college, Ungraded, Not currently in school, Not reported
Ethnicity – Hispanic or Latinx, Not Hispanic or Latinx, Not reported
Race – American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, More than one race, Not reported
Total

For each section (class or group) of the promising intervention (Tier 2) implemented with non-youth participants, how many non-youth participants attended at least one activity of your intervention (Tier 2) in the reporting period? Indicate the unduplicated total number in each category.
Caregivers (such as parents, legal guardians, siblings, extended family; foster parents; "chosen" family members of adolescents): _____
[Note: this count should only include caregivers who are the target population or end-users of a TPP effective program (Tier 1) or a promising intervention to be rigorously tested (Tier 2). Caregivers who are engaged in other aspects of the grant project should be included elsewhere in the stakeholder engagement item.)

Youth-serving professionals (such as social workers, health care providers, teachers, juvenile justice staff, court staff): _____
[Note: this count should only include youth-serving professionals for whom a TPP effective program (Tier 1) or promising intervention to be rigorously tested (Tier 2) are the target population. Professionals who are trained to provide services to youth should be included in the partners item. Professionals who are involved in the systems approaches should be included within the stakeholder engagement item]

For each section (class or group) of the TPP effective program/promising intervention implemented, how many non-youth participants attended at least l supplemental activity (that is, an activity other than the effective program/promising intervention) during the reporting period? Indicate the unduplicated total number in each category.
Caregivers (parents or legal guardians of adolescents): _____
[Note: this count should only include caregivers who attend supplemental activities associated with an effective program/promising intervention such as parent rallies, parent information sessions, or other supplemental activities. Caregivers who are engaged in other aspects of the grant project should be included elsewhere in the systems engagement item.). Caregivers who participate as the target population of the effective program/promising intervention should be counted in the previous item.

Youth-serving professionals (social workers, health care providers, teachers, juvenile justice staff, court staff): _____
[Note: this count should only include any youth-serving professionals who may receive supplemental activities. The youth-serving professionals served by a TPP effective program (Tier 1) or promising intervention to be rigorously tested (Tier 2 should be counted elsewhere). Professionals who are trained to provide services to youth should be included in the training item. Professionals who are involved in the systems approaches should be included within the

stakeholder engagement item]

Dosage of TPP effective programs/promising interventions

These items track the amount of programming received by participants in each section of the TPP effective program (Tier 1)/promising intervention (Tier 2). Program participants are anyone (youth, caregivers, youth-serving professionals) who are the target population for an effective program (Tier 1) or a promising intervention being rigorously evaluated (Tier 2).

What is the average (mean) attendance for program participants in each section? (determined by the percentage of sessions attended by each participant in the section) _____

How many participants in each section received at least 75% of the programming? _____

Observational Fidelity and Quality

All TPP Grantees are expected to observe at least 10% of the sessions of the TPP effective program (Tier 1) or promising intervention being rigorously evaluated (Tier 2). Each session should be observed for fidelity (adherence) to planned activities and overall quality. TPP grantees are expected to develop schedules and implementation plans to ensure that the minimum number of sessions are observed. An observer ideally should be independent from the implementation, familiar with the program model, and may be an internal or external evaluator, supervisor (program director, program coordinator), or a program partner.

In order to track completions, grantees are asked to report general information about sessions implemented. A session is generally a unit of the program delivered within a meeting day of the section. A session may correspond to a full lesson (or module) from the curriculum. In instances where multiple lessons are being implemented in a single day, a grantee may choose to define a session as the entire day's programming, provided that by doing so, the grantee is still able to report observed sessions as a whole number.

Session Information:
Note: these must be reported as whole numbers

Number of sessions (lessons) planned _____
Number of sessions (lessons) completed _____
Number of sessions (lessons) observed _____

Observer reported fidelity
Using the fidelity monitoring tool from the program/intervention developer, report the adherence (%) for observed sessions within each section.
For each effective program/promising intervention session (meeting or lesson) that was observed during the section, what is the percent adherence to the number of activities planned? (Grantees

who observe more than one session per section report the average (mean) adherence percentage for the session)

Adherence = number of activities completed/number of activities planned
_____

Observer reported quality (Based on the TPP observation form).
Rate the overall quality of the session observed on scale of 1 (poor) – 5 (excellent).

Fidelity Process Form (see the TPP Fidelity Process form)
What is the overall total score on the TPP fidelity process form (Scale of 0 – 26).
Stakeholder Engagement Measures

The stakeholder engagement items are designed to track individuals who were engaged within the overall grant project. Engagement could involve providing input on any stage of the overall grant project's implementation, such as, but not limited to, serving on an advisory group, providing feedback on the development of program materials, participating in the continuous quality improvement processes for the project, helping to plan participant recruitment strategy, rating the youth-friendliness of supportive services, etc. The participants served by an actual TPP program (effective program in Tier 1 or promising innovative intervention in Tier 2) should be counted under the reach section and not under stakeholder engagement.

Project stakeholder engagement: How many stakeholders (such as youth, youth-serving professionals, caregivers, potential end-users, or other community members) were engaged within the grant project during the reporting period? Report the number for each category below.

Youth _____
Caregivers _____ (such as parents, guardians, foster parents of youth)
Community members _____ (such as teachers, educators, social workers, health workers, juvenile justice officers, other Youth-serving professionals, faith leaders, business leaders)

Evaluation Template Example (Optional)

TPP Tier 2B Rigorous Impact Evaluation Design Plan Template Optional

Optional Evaluation Design Plan
Study Design and Assignment Methods – Clearly identify the study design for the proposed evaluation. Explains how you would assign participants to the treatment and comparison groups. Describe the assignment mechanism and justify that the proposed mechanism will produce equivalent groups (intervention and comparison conditions). • If a *Randomized Controlled Trial* (RCT) is proposed: Identify the unit of random assignment and align it with the unit of analysis. Describe the procedures to conduct

the random assignment, including who would implement the random assignment, how the procedure would be implemented, and procedures to verify probability of assignment groups, described and generated by random numbers. Discuss any concerns that proposed strategies or approaches may lead to nonequivalent groups.

- If a *Quasi-Experimental Design* (QED), Matching Study is proposed: Clearly identify the unit of matching and align it with the unit of analysis. Describe procedures to carry out the matching. Indicate whether the variables to be used in the matching are supported by precedent in the literature. Describe the methods used to form the comparison group and show the validity of the matching. Describe reasons why the comparison group might differ from the treatment group and threaten internal validity and discuss the ways in which the proposed methods adjust for those differences.

- If a *Regression Discontinuity Design (RDD)* is proposed: Clearly identify the measures and cutoff score and align it with the unit of analysis. Clearly delineate and justify the cutoff score.

Research Questions - Includes a list of research questions that align with the intended goals of the intervention and are clearly related to unplanned Teen Pregnancy Prevention, underlying risk factors, or associated risk behaviors. Identify outcome measures that can be used to reasonably evaluate the effect of the intervention (in particular, at least one sexual behavior outcome). Confirm that you propose an intention-to-treat analysis.

Counterfactual and Context - Describe any services provided to the comparison group and contrast the services to those provided to individuals receiving the intervention. Explain that the services provided to the intervention and comparison groups will be sufficiently different from each other so that the proposed project would be likely to change behavior and create meaningful impacts on the behaviors that you would detect during analysis.

Consent Methods - Provide an explanation of how you will acquire the consent and assent of participants. Describe the estimated rate of consent for study participants and provide a reasonable justification of the expected consent rate.

Data, Instruments & Timing -
Provide a detailed description of the impact survey that you will administer. Clarify that the survey would gather information for each measure that you will use to evaluate the impact of the intervention. Clearly define the timing of data collection relative to the delivery of the intervention. Describes plans to collect implementation data, and impact survey data at 3 points in time from study participants.

Clearly indicate how the evaluation timeline provides adequate time for planning and final analysis by devoting a few months at the start of the grant to planning and piloting and approximately six-eight months at the end of the grant period for analysis and developing reports (you may reference your work plan). Justify that the timing of intervention

administration, data collections (including a complete an analysis of long-term outcomes), and the reporting process, can be completed by the end of the fifth year of grant funding.
If only using administrative data, describe the data sets(s), confirm that their use is feasible for the project, and indicate the timeline for obtaining data (see the next section).

Procedures/Modes of data collection - Discuss a process for protecting human subjects and a timeline for acquiring the approval of an IRB. Identified the IRB to be used during the study. Provide a detailed explanation of the data collection process, including who will collect the data and primary and secondary methods for contacting participants. Describe any systems that will be used to enter and store data. Discuss whether the mode of data collection is the same for the intervention and control groups. Include the expected sample sizes at each data point. If administrative records (such as, but not limited to, school academic records) will be used, describe the source and availability of these data as well as the evaluator's experience using these data sources.

Sampling Plan and Power Analyses – Provide criteria that will be used to select a sample to evaluate the intervention. Provides evidence that a large enough sample exists to evaluate the intervention. Describe your plan to recruit participants for the study and discuss and address any potential challenges you might face when attempting to recruit participants.

Describe how the contact information of evaluation participants will be acquired and regularly updated. Justify that the information is comprehensive enough to allow you to remain in contact with participants throughout the study.

Discuss any methods to maximize the participation of individuals who are part of the evaluation sample – both treatment and control/comparison groups. Explain how the methods discussed seem likely to be approved by the IRB and would successfully improve participation. Describe and justify the expected survey response rates.

Estimate statistical power for the study and explain why the power is consistent with study design. Describe the statistical power analysis used to arrive at the sample size. Include the Minimum Detectable Effect (MDE) that has an 80% chance of being statistically significant at a specific alpha level, for each outcome. Describe the outcomes and assumptions used in the statistical power calculations. Indicate how the assumptions for the MDE calculation are consistent with information presented earlier in the proposal (e.g., the number of participants in the study, after non-consent and non-response). Provide sufficient justification as to why the study will find an effect larger than the MDE calculated. If you plan to conduct analyses of subgroups, present additional statistical power analyses to estimate those MDEs.

Evaluation Limitations Describe any limitations of the proposed evaluation and how you will attempt to address the limitations described. Explain how you will address potential conflicts of interest and ensure independence of the intervention implementation and the evaluation.

7. References

Administration of Children and Families, Office of Planning, Research, and Evaluation . (2016, March 16). *Common Framework for Research and Evaluation.* . Retrieved from https://www.acf.hhs.gov/sites/default/files/opre/acf_common_framework_for_research_and_evaluation_v02_a.p

Centers for Disease Control and Prevention. (n.d.). *Transparent Reporting of Evaluations with Nonrandomized Designs, Centers for Disease Control and Prevention.* Retrieved November 22, 2022, from https://www.cdc.gov/trendstatement/index.html

Centers for Disease Control and Prevention, Division of STD Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention (S.) (2020). Sexually Transmitted Disease Surveillance, 2020.. Retrieved November 15, 2022 from https://www.cdc.gov/std/statistics/2020/default.htm

Centers for Disease Control and Prevention, National Center for Health Statistics, Vital Statistics (V. S.) (2020). *Vital Statistics*. Retrieved from https://www.cdc.gov/nchs/fastats/teen-births.htm

Healthy People. (2030). Retrieved November 15, 2022 from https://health.gov/healthypeople

James, S. M. (2009). Sexual Risk Behaviors among Youth in the Child Welfare System. *Children and Youth Services Review*, 31: p. 990-100.

Lugo-Gil, J. A. et al. (2018). Updated Findings from the HHS Teen Pregnancy Prevention Evidence Review: August 2015 Through October 2016. Washington, DC: Brief submitted to the Office of the Assistant Secretary for Planning and Evaluation. Retrieved November 15, 2022 from: https://tppevidencereview.youth.gov/pdfs/Summary_of_findings_2016-2017.pdf

Mathematica (2022). Teen Pregnancy Prevention Evidence Review (TPPER). Identifying Programs That Impact Teen Pregnancy, Sexually Transmitted Infections, and Associated Sexual Risk Behaviors. Review Protocol, |Version 6.0 Retrieved December 1, 2022 from https://tppevidencereview.youth.gov/pdfs/TPPER-Review-Protocol-Version-6.0.pdf

Office of Adolescent Health. (2017, September). Tier 1B Grant Implementation Study Planning. Retrieved November 1, 2022 from: https://opa.hhs.gov/sites/default/files/2020-07/tier-1b-grant-implementation-study-planning-brief.pdf
Office of the Assistant Secretary for Health/Office of Disease Prevention and Health Promotion. Healthy People 2030 Questions & Answers.(2022, July 2). *Healthy People 2030.* Retrieved November 18, 2022, from Healthy people 2030 questions & answers. Retrieved December 1, 2022 from: https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers#q9.

Office of Minority Health. (n.d.). CLAS, cultural competency, and cultural humility. Retrieved February 2022, from Think Cultural Health: https://www.minorityhealth.hhs.gov/Assets/PDF/TCH%20Resource%20Library_CLAS%20CLC%20CH.pdf

Saewyc, E. (2014). *Adolescent Pregnancy Among Lesbian, Gay, and Bisexual Teens in the International Handbook of Adolescent Pregnancy (editors: Cherry, A. and Dillon, M.)* International Handbook of Adolescent Pregnancy: Medical, Psychosocial, and Public Health Reponses, pp. 159-169. Retrieved from https://doi.org/10.1007/978-1-4899-8026-7_8

Sedgh G., Finer L.B., Bankole A., Eilers M.A., Singh S. (2015). Adolescent pregnancy, birth, and abortion rates across countries: levels and recent trends. *Journal of Adolescent Health*, 56(2): 223-30.

Sedlak, A. and Bruce, C.(2010). *Youth's Characteristics and Backgrounds: Findings from the Survey of Youth in Residential Placement.* U.S. Department of Justice, Office of Justice Programs, and Office of Juvenile Justice and Delinquency Prevention, Editors. Retrieved October 15, 2022 from https://ojjdp.ojp.gov/library/publications/youths-characteristics-and-backgrounds-findings-survey-youth-residential