
DEPARTMENT OF
HEALTH AND HUMAN SERVICES
OFFICE OF THE
ASSISTANT SECRETARY FOR HEALTH

Office of Population Affairs

Funding Opportunity: FY2020 Teen Pregnancy Prevention (TPP) Tier 2,

Phase II Rigorous Evaluation of Promising Interventions

Opportunity Number: AH-TP2-20-001

Amended March 24, 2020

Application Due Date:

Friday, May 1, 2020 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

Office of the Assistant Secretary for Health / Office of Population Affairs

FUNDING OPPORTUNITY TITLE

FY2020 Teen Pregnancy Prevention (TPP) Tier 2, Phase II Rigorous Evaluation of Promising Interventions

ACTION

Notice

ANNOUNCEMENT TYPE

Competitive Cooperative Agreement

FUNDING OPPORTUNITY NUMBER

AH-TP2-20-001

CFDA NUMBER AND PROGRAM:

93.297 Teen Pregnancy Prevention

DATES

Application Deadline: Friday, May 1, 2020 by 6:00 PM Eastern.

Technical Assistance: Webinar Wednesday, February 19, 2020 at 2:30 PM Eastern.

EXECUTIVE SUMMARY

The Office of Population Affairs announces the availability of funds for Fiscal Year (FY) 2020 cooperative agreement awards under the authority of Division A, Title II of the Further Consolidated Appropriations Act, 2020 (Public Law No. 116-94).

This notice solicits applications for the **FY2020 Teen Pregnancy Prevention (TPP) Tier 2, Phase II Rigorous Evaluation of Promising Interventions (TPP Rigorous Evaluation)**. The goal of this Funding Opportunity Announcement (FOA) is to rigorously evaluate promising interventions that could contribute to adolescent optimal health, prevent teen pregnancy, and reduce sexually transmitted infection (STI) rates. The applicant is expected to evaluate interventions that already have project merit, positive preliminary evidence, readiness, and feasibility. This funding will support rigorous evaluations designed to answer important research question(s) about the impact and implementation of interventions. Projects may conduct either efficacy or effectiveness studies and must be able to complete the project within the three-year period. OPA intends to make approximately \$5 million available for an estimated five to ten awards. The amount of funding an applicant may request ranges from \$500,000 to \$1 million per year for a three year period (three 12-month budget periods).

This FOA continues efforts supported through the FY2018 and FY2019 Phase I New and Innovative Strategies (Tier 2) to Prevent Teen Pregnancy and Promote Healthy Adolescence, but is open to any applicant (not just those previously funded through Phase I) who can meet the following expectations for Phase II.

1. Meaningfully Contribute to Optimal Health, Prevent Teen Pregnancy and Reduce STIs; Demonstrate Project Merit and Preliminary Positive Evidence
2. Demonstrate Readiness and Feasibility of the Intervention and Evaluation
3. Conduct High-Quality Implementation
4. Rigorously Evaluate the Intervention
5. Collaborate with Partners, Participants, and Stakeholders
6. Monitor and Improve the Project

7. Communicate Project Activities; Disseminate Results

8. Manage the Project and Ensure Capacity

For purposes of this funding opportunity announcement, “project” will refer to all activities described in the grant application and funded by the grant; “evaluation” will refer to the rigorous implementation and impact research of interventions; “intervention” will refer to the innovative programs, models, component(s), products, approaches, or practices to prevent teen pregnancy and reduce STIs; and “counterfactual” will refer to the comparison or control group(s) in the evaluation.

FUNDING OPPORTUNITY DETAILS

A. DATES

1. **Application Deadline**

Your application is due Friday, May 1, 2020 by 6:00 PM Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and time. If you do not submit your application by the specified deadline, we will return it to you unread. 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, HHS/Office of the Assistant Secretary for Health (OASH) Office of Grants Management (OGM). To obtain an exemption, you must request one via email from the HHS/OASH OGM, 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 DUNS number; your organization's name, address and telephone number; the

name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (for example, GRANT#####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to ogm.oash@hhs.gov. Note: 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.

The HHS/OASH OGM 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 F.8 ("Other Submission Requirements") for information on application submission mechanisms.

To ensure adequate time to submit your application successfully, HHS/OASH recommends that you register as early as possible in Grants.gov since the registration process can take up to one month. You must register an authorizing official for your organization. HHS/OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to <http://www.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.

2. Technical Assistance

A technical assistance webinar for potential applicants will be held on February 19, 2020, at 2:30 PM Eastern. Details to log-in to the webinar will be available on the OPA website at <https://www.hhs.gov/opa/grants-and-funding/index.html>.

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

B. PROGRAM DESCRIPTION:

The Office of the Assistant Secretary for Health, Office of Population Affairs announces the availability of funds for Fiscal Year (FY) 2020 cooperative agreement awards under the authority of Division A, Title II of the Further Consolidated Appropriations Act, 2020 (Public Law No. 116-94). The primary focus of the Office of the Assistant Secretary for Health is leading America to healthier lives, especially for those who are most vulnerable, including those who have suffered historic disparities. In support of this vision, the Office of Population Affairs promotes health across the reproductive lifespan through innovative, evidence-based adolescent health and family planning programs, services, strategic partnerships, evaluation, and research. The Teen Pregnancy Prevention (TPP) Program is designed to give youth the information and skills to promote optimal health and prevent teen pregnancy across the United States, especially among those who are most vulnerable.

1. Background

There has been much progress in reducing teen pregnancy and teen birth. However, the current teen birth rate in 2018 of 17.4 per 1,000 females aged 15-19 is still much higher than other western industrialized nations [1,2], and we continue to see disparities by race, ethnicity, and among our most vulnerable populations, including homeless youth, those living in foster care, or involved with the juvenile justice system [2,3,4]. Further, STI rates reached an all-time high in the United States in 2018 [5], with significant concern for transmission of STIs in adolescents. Syphilis rates jumped 34% from 2017 for females age 15-19. Approximately 62% of all chlamydia cases (1,087,277) were reported in individuals aged 15-24, and 15-19-year-old males and females experienced an increase of 3.7% and 1.3%, respectively, from 2017. Females in this age group also reported the second-highest rate of gonorrhea, after females age 20-24. Herpes continues to be prevalent. Finally, while not as common in adolescents, individuals aged 13-24 made up 21% of all new HIV diagnoses in 2017 [6].

The Office of Population Affairs' (OPA) goal is to ensure optimal health beginning in adolescence and continuing across the reproductive lifespan through lifestyle change. Optimal health is a dynamic balance of physical, emotional, social, spiritual, and intellectual health. Lifestyle change can be facilitated through a combination of learning experiences that enhance awareness, increase motivation, and build skills and, most important, through the creation of opportunities that open access to environments that make positive health practices the easiest choice [7]. OPA takes an optimal health approach in supporting adolescents to lead healthier lives by avoiding and/or reducing sexual risks, preventing teen pregnancy, and reducing STIs. The optimal health model can be applied to a broad range of programs proven effective at preventing teen pregnancy and associated risk behaviors, including positive youth development, sex

education, abstinence education, and programs designed for diverse populations and settings. Under this framework, OPA also promotes healthy adolescence through the Adolescent Health: Think, Act, Grow® (TAG) Five Essentials, including: positive connections with supportive people; safe and secure places to live, learn, work and play; access to high quality and teen-friendly health care; opportunities to engage as learners, leaders, team members, and workers; and coordinated adolescent and family-centered services.

New and innovative programs to prevent teen pregnancy and improve optimal health are being developed and evaluated through investments by the U.S. Department of Health and Human Services and others. The Personal Responsibility Education Innovative Strategies Program (PREIS) at ACF, for example, has funded research and demonstration projects that implement innovative strategies for preventing pregnancy among youth aged 10-19 years old. Through OASH, in 2015, five-year investments were made to enable and support early innovation to advance adolescent health and prevent teen pregnancy (FY15 TPP Tier 2A); through this funding, new technologies and programs have been developed. At the same time, teen pregnancy prevention programs were funded to undergo rigorous evaluation (FY15 TPP Tier 2B). More recently, in 2018, OPA invested in Phase I New and Innovative Strategies (Tier 2) to Prevent Teen Pregnancy and Promote Healthy Adolescence. These projects were funded for two years to conduct formative evaluations of new and innovative programs.

This FOA continues efforts supported through the FY2018 and FY2019 Phase I New and Innovative Strategies (Tier 2) to Prevent Teen Pregnancy and Promote Healthy Adolescence, but is open to any applicant (not just those previously funded through Phase I). The purpose of this FOA is to rigorously evaluate interventions that already have project merit, positive preliminary evidence, readiness, and feasibility. All applicants are expected to justify that their intervention is

ready for rigorous evaluation, and their rigorous evaluation would be ready to **start within the first three months of the project period**. Successful applicants will have fully developed and tested interventions, which show positive, preliminary evidence from their formative evaluation. Formative evaluation results should show demand and need for the intervention, directly from participants. Additionally, successful applicants will demonstrate that intervention materials are already developed and tested, including all supporting materials such as training or intervention manuals. Furthermore, successful applicants will have their rigorous evaluation designed and evaluation tools available.

Although many programs have been developed and evaluated, there is still much to learn about what works, how, for whom, and why. Additionally, there is a lack of effective programs for key areas and populations that face health disparities. This funding will support rigorous evaluations designed to answer important research question(s) about the impact and implementation of interventions. Projects may conduct either **efficacy or effectiveness studies and must be able to complete the project within the three-year period**.

In order to ensure health equity and promote optimal health, OPA is particularly interested in rigorous evaluations of promising interventions in populations and settings with great need and those that demonstrate 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 homeless youth, or for caregivers. Additionally, OPA is interested in projects that impact not only individuals but also the systems within which individuals are situated.

Applicants are expected to evaluate interventions that address key health disparities and have the potential to make a significant contribution to the field. All interventions proposed should

already have project merit, positive, preliminary evidence, and readiness and feasibility for a rigorous evaluation. **Successful projects will meet the following expectations for the FY 2020 Teen Pregnancy Prevention (TPP) Tier 2, Phase II Rigorous Evaluation of Promising Interventions (TPP Rigorous Evaluation):** (a) Meaningfully Contribute to Optimal Health, Prevent Teen Pregnancy, and Reduce STIs; Demonstrate Project Merit and Preliminary Positive Evidence; (b) Demonstrate Readiness and Feasibility of the Intervention and Evaluation; (c) Conduct High-Quality Implementation; (d) Rigorously Evaluate the Intervention; (e) Collaborate with Partners, Participants, and Stakeholders; (f) Monitor and Improve the Project; (g) Communicate Project Activities; Disseminate Results; and (h) Manage the Project and Ensure Capacity.

2. **Expectations**

a. Meaningfully Contribute to Optimal Health, Prevent Teen Pregnancy, and Reduce STIs; Demonstrate Project Merit and Preliminary Positive Evidence

Applicants are expected to meaningfully contribute and show how the project has the potential to improve optimal health, prevent teen pregnancy, and reduce STIs. OPA is especially interested in targeting resources to populations disproportionately impacted by teen pregnancy and STI rates, to reduce health disparities and to improve equity and optimal health.

Interventions supported by this funding are expected to be innovative and already have compelling, positive preliminary evidence from their formative evaluation, including effects on target outcomes. The intervention should also have widespread support from participants and stakeholders and be a good fit for the target population and setting. In order to make a meaningful contribution, interventions evaluated under this funding are expected to have the potential to scale

and be replicated by others. Applicants should demonstrate the potential for scale of the intervention upon project completion.

b. Demonstrate Readiness and Feasibility of the Intervention and Evaluation

1) Intervention Readiness and Feasibility

In addition to making a meaningful contribution, OPA expects applicants to have all intervention materials finalized, ready, accessible, and available for implementation. The intervention and supporting materials should be fully developed, and applicants or their partners should have implemented the intervention multiple times. Materials must also already be medically accurate and age-appropriate and should be trauma-informed and user-centered; changes to the intervention should have already been made based on participant feedback. Procedures and activities of the intervention are expected to be clear, including mode of delivery, frequency, duration, location, setting, and monitoring mechanisms. The applicant is expected to describe the procedures for intervention implementation and the training necessary for staff. Applicants are expected to ensure feasibility of implementation within their application but also throughout the project period. This includes but is not limited to a reasonable timeline and Memorandums of Understand (MOUs) or other agreements with partners to begin at the start of the project period. This information will also be covered in the “Conduct High-Quality Implementation” and “Capacity and Project Management” expectation.

Applicants who choose to use any copyrighted curriculum materials in their proposed project must include a signed agreement with the developer or purveyor of the materials that demonstrates that the applicant has permission to use the materials as planned. This should include, but is not limited to, permission to use the materials as proposed in the application and/or alter them as needed for compliance with OPA medical accuracy review.

2) Evaluation Readiness and Feasibility

The evaluation is expected to be ready and feasible at the time of award, including clear plans for the counterfactual (comparison or control group); any services, programming, or materials proposed for the counterfactual group must be ready for implementation and accessible to the applicant by the time of grant award. Methods and procedures for participant recruitment, consent/assent, and study group formation should be reasonable and feasible for the proposed project and three-year timeline. All project activities, including data collection, data analysis, and reporting, are expected to be completed within three years, which includes dedicating the final six months to analysis and reporting. Applicants are expected to propose a sample size for their project that can detect impacts and account for attrition or other potential loss of data (see “Conduct Rigorous Evaluation” expectation). Evaluation designs should include power calculations based on the proposed sample size; evaluation designs are expected to be sufficiently powered to detect impacts on the primary research questions. Applicants are expected to have IRB approval or a waiver by the start of the project period and be ready to begin their evaluation immediately upon receipt of funding. All MOUs or agreements between the applicant and their key implementation partners (such as implementation sites, independent evaluator, and program implementers) should be in place for the evaluation to begin immediately at the start of the project period. Applicants may include all signed agreements that can be secured prior to the application due date in an Appendix. If recommended for funding, agreements must be provided prior to the project start date. (also see “Manage the Project and Ensure Capacity” expectation).

c. Conduct High-Quality Implementation

It is expected that during the project, the awardee will conduct high-quality implementation of the intervention, including but not limited to: maintaining fidelity, quality assurance, high dosage, intervention saturation, appropriate materials, staff coordination and management, qualified facilitators, participant engagement and satisfaction, and stakeholder support. The applicant should describe the implementation settings, including partners and the status of agreements with partners. High-quality implementation should also be realized through adequate training and codified procedures for the intervention and, if applicable, the counterfactual. It is required that throughout the project, the implementation will be medically accurate and age-appropriate and expected that it will be trauma-informed and user-centered for both the intervention and counterfactual. Additionally, the awardee is expected to use implementation findings to improve the implementation and delivery.

Given that implementation and research is likely to occur in environments that have been historically under-resourced and marginalized, there is an expectation to appropriately understand the context and big picture in which the issues of teen pregnancy and STIs exist. Systems thinking can help applicants demonstrate an understanding of contextual factors, relationships between those factors, and how things can change over time. The applicant should explain an understanding of the context, big picture, and how their intervention and research is situated. Additionally, the applicant should explain underlying assumptions and inhibiting or enabling factors related to the project. Awardees, throughout their projects, are expected to adequately consider the complexity of the implementation environment.

d. Conduct Rigorous Evaluation

Rigorous evaluations can include either a randomized control trial (RCT) or a quasi-experimental design (QED) with counterfactual condition, and should be the most robust possible design that is feasible for the intervention. RCTs are experiments that randomly assign participants into different, unique groups: the treatment or intervention group and the control or counterfactual. A QED forms intervention and counterfactual groups through methods other than random assignment of participants. A QED may be used for impact evaluations when random assignment is not an option and include methods such as Propensity Score Matching (PSM), Regression Discontinuity, and Interrupted Time Series (ITS), among others.

Evaluations supported by this funding can be an efficacy or effectiveness study. 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 [8]. Applicants are also expected to conduct an implementation evaluation, based on implementation science practices and designed to answer questions about how and why an intervention works.

Applicants are expected to describe the type of design selected and if it is an efficacy or effectiveness trial. They should describe the full study design, including the implementation and impact evaluation. Research questions are expected to assess both behaviors and implementation outcomes and clearly align with the intervention and theory of change. Primary and secondary questions should be determined, and evaluation designs are expected 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). OPA expects that all studies will have a counterfactual, and there will be baseline equivalency between the intervention group and counterfactual.

Additionally, it is expected for the treatment and counterfactual groups to be different enough to allow for a meaningful test. For RCTs, the unit of random assignment is expected to be clearly identified and aligned with the unit of analysis; for QEDs, the applicant is expected to describe the formation of the counterfactual. Differences between groups should be described along with strategies to minimize potential contamination, should this be a potential concern.

The applicant is expected to have data collection instruments that have already been tested or administrative data which can be accessed. The applicant is expected to describe how they plan to estimate the causal impact of the intervention, describe the minimum detectable effect (MDE) size needed for an impact, and explain how the MDE was calculated. Awardees will collect, analyze, and report on the data, providing updates to key stakeholders regularly.

Awardees are expected to be aware of and address limitations, bias, and possible threats to internal and external validity. The evaluation is expected to be conducted 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 from the intervention (see “Manage the Project and Ensure Capacity” section). As a condition of the grant award, recipients will be required to participate in Evaluation Technical Assistance from OPA. Further, as a condition of the grant award, all successful recipients will be required to participate in any OPA-directed Federal evaluation, if selected, and if funding for such an evaluation becomes available. Recipients will be expected to submit a final evaluation report to OPA at the end of the grant award; specific guidance on the format will be provided after the grant is awarded.

e. Collaborate with Partners, Participants, and Stakeholders

Given the purpose of the funding to improve optimal health of youth, prevent teen pregnancy, and reduce STIs rates, it is important to collaborate and maintain partnerships with

those involved in the project, including partners, participants, and stakeholders. OPA expects that applicants will demonstrate how they have previously engaged participants and stakeholders, maintained a collaborative environment, and structured their approach accordingly. Additionally, OPA does not expect one organization to carry out the entire project; rather, the applicant and their key partners should have the collective expertise necessary to successfully accomplish the goals and objectives for the implementation and evaluation. Collaborative partnership is expected between the evaluator and intervention teams, and with OPA. The awardee is responsible for ensuring all partners meet the expectations successfully and fulfill their roles.

f. Monitor and Improve the Project

OPA expects awardees to monitor the overall project and, based on key findings, make improvements to the project. This could include improvements to the evaluation or implementation procedures, for example. The monitoring and improvement plan should include performance measures for the overall project. Furthermore, awardees will use the information garnered from the evaluation, monitoring, and performance measures to determine next steps for the intervention and project. This could include positioning the intervention for widespread dissemination and scale, or it could include changing the design of the intervention based on findings and preparing for another type of evaluation.

All recipients are expected to collect a common set of performance measures to assess project implementation and use measures for monitoring and improving. See Appendix C for a draft set of performance measures (subject to change). Recipients must collect all performance measures and report to OAH on a semi-annual basis. Recipients should review relevant state laws, organizational policies, and other administrative procedures of their sites or partner organizations

to ensure the feasibility of data collection. Recipients should obtain any necessary permissions to collect required data.

g. Communicate Project Activities and Disseminate Results

Communicating information is vitally important to project success, sustainability, and to stakeholders. The public, internal stakeholders, and external stakeholders should be informed about the activities of the project throughout the entire project period. Additionally, OPA expects recipients to carefully document the results of the intervention, using best practices for reporting such as the CONSolidated Standards of Reporting Trials (CONSORT) for RCTs [9] or the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) for QEDs [10]. Recipients are expected to present results at local, state, and national professional and academic conferences and meetings, and to share findings in respected journals or other publications and OPA reports.

h. Manage the Project and Ensure Capacity

The applicant should propose a team, partnerships, and structure to successfully accomplish all expectations of the grant. OPA expects the applicant to provide an overview of the different organizations involved, along with key team members. Key team members should have resumes with credentials, expertise, and capacity that align with their positions. The applicant, in particular, should clearly articulate who will serve as the evaluation and intervention leads and include the resumes with relevant experience. The project should be conducted 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 from the intervention.

A visual depiction of the project structure, including key partners and roles, should be included. The applicant should outline how they plan to manage the project. For all partnerships, the application should describe how the partner will contribute to the project and clearly outlines roles, responsibilities, and expectations, and may include a signed Memorandum of Understanding (MOU) if available. Awardees should assess the professional development needs of staff on a regular basis and use the results to develop a plan for providing ongoing professional development and support for staff.

Awardees may use up to the first three months to complete project planning and finalize agreements. However, this funding is designed to support projects that are ready, feasible, already have project merit, and demonstrate positive preliminary results.

This award is a cooperative agreement, a form of assistance that allows for substantial involvement by OPA. In addition to the usual monitoring and technical assistance provided under the cooperative agreement (e.g., assistance from assigned Federal project officer, regular conference calls, occasional site visits, ongoing review of plans and progress, participation in relevant meetings, provision of training and technical assistance), OPA's substantial programmatic involvement will include:

- 1) Prior approval for change of time that Key Personnel are dedicated to the project and for replacement of Key Personnel. Key Personnel are those staff that are responsible for the day-to-day project management as well as the lead evaluator.
- 2) Identification of other awardees and organizations with whom the awardee may be asked to develop cooperative and collaborative relationships and partnerships.
- 3) Assisting the awardee to establish, review, and update priorities for activities conducted under the auspices of this cooperative agreement.

- 4) Consulting with the awardee throughout the preparation and dissemination of materials related to the project.
- 5) Review and approval of implementation plans, evaluation plans, data collection tools and measures, and monitoring plans.
- 6) Ensuring intervention materials prior to use in the project are medically-accurate, age-appropriate, trauma-informed, and user-centered.

C. AUTHORITY

Division A, Title II of the Further Consolidated Appropriations Act, 2020 (Public Law No. 116-94).

D. FEDERAL AWARD INFORMATION

The Office of Population Affairs intends to make funds available for competing cooperative agreements.

We will fund awards in annual increments (budget periods) and generally for a project period up to 3 year, although we may approve shorter project periods. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. 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, and adequate stewardship of Federal funds.

Award Information

Estimated Federal Funds Available: \$5,000,000

Anticipated Number of Awards: 5-10

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: July 15, 2020

Estimated Period of Performance: Not to exceed 3 years

Anticipated Initial Budget Period Length: 12 months

Type of Award: Cooperative Agreement. Agency substantial involvement outlined above in Program Description.

Type of Application Accepted: Electronic via Grants.gov ONLY unless an exemption is granted

E. ELIGIBILITY INFORMATION

1. Eligible Applicants.

Any public or private entity, including faith-based, community-based, and Indian Tribes or Tribal organizations are eligible to apply.

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget

3. Other Eligibility Information

None

4. Application Disqualification Criteria

If you successfully submit an application, we will screen it to ensure it meets the below requirements. 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 www.grants.gov (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section (A.1) 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) HHS/OASH/OGM deems your application eligible according to section E.1 Eligible Applicants.
- (d) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.
- (e) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” inch page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points.
- (f) Your Project Narrative must not exceed 50 pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).

(g) Your total application, including the Project Narrative plus Appendices, must not exceed 100 pages. NOTE: the items listed in “(f)” immediately above that do not count toward total page limit.

(h) Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.

(i) Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.

F. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at <http://www.grants.gov/>. You can find it by searching on the CFDA number shown on page 2 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

Office of Grants Management

Phone: 240-453-8822

Email: ogm.oash@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.

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

include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria. 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 when printed on 8.5” X 11” paper by HHS/OASH/OGM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

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.

b. Appendices Format

Your Appendices should include any specific documents outlined in Section D.2.iii., under the heading “Appendices” in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, 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. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

Summarize your project in 250 words; outline the project's name, intervention, setting, and target population; explain the project, structure, evaluation design, and expected contribution.

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

1) Project Merit, Contribution, and Evidence

- What is the specific problem that your project addresses? What is the context for this project? Where will the project take place, and with whom? How will you address historical, structural, and environmental factors that could impact your project? What are your underlying assumptions for this project?
- In brief, what are your intervention, theory of change, and evaluation design?
- How do your project, intervention, and evaluation contribute to the field? Why is this project important?

- How does your intervention meet the needs of your participants? How is it innovative? How is it a good fit for the population? Please verify with supporting evidence directly from your participants.
- What previous research has been conducted? How does this evaluation build from the previous research? Why is your specific evaluation necessary to conduct?
- What is the preliminary evidence of effectiveness for the intervention? Were there positive effects on key outcomes?
- How many times has the intervention been implemented already? What were the circumstances, and how has it evolved?
- Could this intervention, if proven impactful, scale and be replicated by others? How? What key barriers might you face?

2) Technical Approach

(a) Intervention and Theory of Change

- How is your intervention and theory of change ready for an evaluation? What is the status of your intervention materials, supplemental materials such as trainings and staff requirements? Please demonstrate and justify that materials are accessible, available, final, and already trauma-informed, medically-accurate, age-appropriate, and user-centered.
- Please include a visual depiction of your theory of change as an appendix.

(b) Counterfactual

- What is your counterfactual? What curriculum, materials, or services, if any, will the counterfactual group receive, and who will provide the programming to the counterfactual participants? Indicate whether a business-as-usual (BAU) counterfactual is planned. Are the proposed counterfactual materials/services, trainings, staff requirements ready for implementation, and available by the start of the grant project? Please demonstrate, if applicable, counterfactual materials are accessible, available, final, and already trauma-informed, medically-accurate, age-appropriate, and user-centered.
- How will your project ensure contrast between the intervention and the counterfactual groups? How will you assess the extent of diffusion of the program to the intervention group and counterfactual? What is your plan for assessing whether the counterfactual group received programming or BAU?

(c) Implementation

- During the project period, how will you implement the intervention? Why? Has this been conducted before, and did it work? What benchmarks and monitoring tools do you have for successful implementation?
- Do you have assurance from all implementation partners that show that implementation is ready to begin immediately upon receipt of funding?

(d) Evaluation Plan

- What is your evaluation design (i.e., randomized control trial, quasi-experimental design)? Will you be conducting an efficacy or effectiveness study? How did you use the most robust possible design? Please justify
- What are the primary and secondary research questions or hypotheses you are testing? How will your questions assess both impact and implementation evaluation? *Ensure research questions are phrased such that groups can be compared to understand the net effect of intervention and differences. Additionally, ensure the confirmatory research question(s) represent(s) the main impact question(s) for the primary outcome that the study can address with a known level of statistical precision (based on statistical power).*
- How will the counterfactual group(s) be formed or assigned? Please describe strategies to minimize potential contamination (if this is a potential concern). If applicable, include recruitment, consent, assignment, tracking, and retaining methods.
- What outcomes are you measuring? Why? What implementation factors are you measuring? Why? How does this relate back to your theory of change? What data will be collected to support the impact evaluation and implementation evaluation? Describe how existing data collection instruments or data sources align with the research questions, evaluation, intervention, and theory of change?

- What systems, procedures, and processes will you use to collect data? Why?
 - Estimate the statistical power. Describe whether statistical power is consistent with the study design, has an 80 percent chance of being statistically significant at the $p < .05$ level, and includes additional power analyses for plans to analyze subgroups.
 - What are your plans for measuring the level of services actually received by participants? How will you assess if an adequate amount of the intervention was delivered to participants? How will you measure quality of the intervention delivery?
 - How will you estimate causal impact of the intervention? What is your minimum detectable effect (MDE) size? What is your sample size and power for detecting an impact?
 - What limitations are there? What potential bias is there in your plan? What possible threats are there to internal and external validity? How will these be addressed?
- (e) Readiness and Feasibility of Rigorous Evaluation
- What is the status of your IRB approval?
 - What data instruments will be used, and have they been developed and tested already? If using administrative data, where will you acquire this data, and have you already received permission?
 - Will you have agreements in place with all external partners (such as implementation sites, independent evaluator, and program

implementers if applicable) to conduct the evaluation? What is the current status of on forming and executing those agreements

- Can the evaluation successfully be completed within three years? Will follow up data collection end by December 2022 to allow enough time for analysis? Include a timeline to show key activities during the project period.

(f) Monitor and Improve the Project

- How will you monitor the project overall? What will you monitor, and why? What will be the frequency of monitoring activities?
- How will you use data, including required TPP performance measures, to improve the project? What is your process for improving the project overall?

(g) Collaboration, Communication, and Dissemination

- How will the project work with partners, participants, and stakeholders to maintain a collaborative environment? How will the project equitably engage participants from the target population? What about key stakeholders from the community?
- What is the communication plan for the project overall? How will you apply best practices to disseminate results, including to participants and stakeholders?

3) Project Management and Capacity

- Please provide an overview of the implementing and evaluating organization, along with the organizational structure of the project. How will the project be managed?
- Who are the partners (if any), what skills and expertise do they contribute, and how will they be monitored? Please indicate the status of the necessary agreements and what needs to be done to complete them.
- Who are the key team members? Does the lead evaluator have experience receiving IRB approval, conducting rigorous evaluation, and publishing results? Does the implementation staff have experience with the target population and the intervention?
- Provide a brief summary list, and include training, qualifications, and experience with similar projects and target populations. In addition, provide resumes for leadership members, such as lead evaluator(s) and lead interventionist(s).
- Are there any perceived or actual conflicts of interest? How will you ensure neutrality and independence between the evaluation and intervention?

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. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

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).

Please be sure to carefully review section F.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. Provide a budget justification, which includes explanatory text and line-item detail, for the 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, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not** include costs beyond the first budget year 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 year.

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. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting 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 (when required) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying. "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

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel.

1) Object Class Descriptions and Required Justifications

(a) Personnel Description

Costs of staff salaries and wages, excluding benefits.

(b) Personnel Justification

Clearly identify the project director or principal investigator, 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.6 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.

(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.

(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. (Note: 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.

Note: Whenever you intend to delegate part of the project to another agency, you must provide a detailed budget and budget narrative for each subrecipient/contractor, by agency title, 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 delegated, the estimated costs, and the process for selecting the delegate agency.

(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.

- 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.”

This 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.

(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, 75.407 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. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. 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 project period for fully-funded awards, even if the justification by budget period, or by project period 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). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA 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. Note, 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 project period for fully-funded awards). If your application does not include the required supporting documentation for a matching requirement, it will not be disqualified from competitive review; however, it may impact your score under the evaluation criteria in Section G.1 of this announcement.

c. Plan for 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 Office of Grants

Management and Payment Management Services as well as timely and appropriate withdrawal of cash from the Payment Management System.

d. 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

Include a detailed work plan for each year of the three-year project period. The work plan should reflect, and be consistent with, the Project Narrative and Budget Narrative. 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 goals, SMART (specific, measurable, achievable, realistic, and time-phased) objectives, activities to accomplish each objective, and, for each activity, the person(s) responsible, timeline for completing activities, and measures of success. The work plan should be aligned with the expectations in this FOA.

2) Project Timeline

Include a separate project timeline for all activities; the timeline should reflect key evaluation activities including data collection, analysis, and reporting and key intervention activities such as training and sustainability.

3) Organizational Chart

The organization chart should show how the project will be structured and organized, including different partners, staff, participants, and implementation settings.

4) Visual Depiction of Project (Theory of Change/Logic Model)

Include a visual depiction for the project, such as a logic model, results framework, systems map, theory of change, or conceptual model. The visual depiction is expected to reflect the intervention and include long-term outcome(s), medium/short-term outcome(s), major milestone activities, and key assumptions.

5) Curriculum Vitae for Key Project Personnel

Submit the curriculum vitae and/or resumes for the Project Director and other proposed key staff. Key personnel includes those individuals who will implement and evaluate the intervention.

6) Memoranda of Understanding (MOUs) or Letters of Commitment (LOCs) or other agreements such as contracts

Memoranda of Understanding (MOUs) or Letters of Commitment (LOCs) may be included with the application for all organizations and entities that have been specifically named as a partner. Finalized MOUs or LOCs must be provided before any award will be made. The signed statements should detail the roles and resources that will be provided, or activities that will be undertaken, in support of the applicant; demonstrate current commitment from the partners to the project being proposed in the application; and describe the organization's expertise, experience, and access to the selected population(s).

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

You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain.

You will find instructions on the Grants.Gov web site as part of the organization registration process at <http://www.grants.gov/web/grants/applicants/organization-registration.html>.

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.

If 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/fsd->

[gov/answer.do?sysparm_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm_search=kb0013](https://www.fsd.gov/answer.do?sysparm_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm_search=kb0013)
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A quick start guide for registrants is available at https://www.sam.gov/sam/transcript/Quick_Guide_for_Grants_Registrations.pdf. 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.

If your organization is already registered in SAM, 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.

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, this information must be included on a Notice of Award. For instructions on updating this information see https://gsafsd.service-now.com/fsd-gov/answer.do?sysparm_kbid=c3d982af6fb8d5006f348d412e3ee47e

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.

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.

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 DUNS number at the time you, the recipient, make a sub-award.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in Section A.1 of this announcement**. 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 <http://www.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.**

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 the Budget Narrative section of this announcement 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>.

1) Pre-Award Costs

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. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the HHS awarding agency.

Pre-award costs are not allowed.

2) 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 2020, the Executive Level II salary is \$197,300. 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 <i>actual</i> base full time salary: \$350,000	
50% of time devoted to project, i.e. .5 FTE	
Direct salary (\$350,000 x .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 <i>adjusted</i> to Executive Level II: \$197,300	
Direct salary (\$197,300 x .5)	\$98,650
Fringe (25% of salary)	\$24,663
Total amount allowed	\$123,313

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

a. Electronic Submission

HHS/OASH requires 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 <http://www.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. HHS/OASH strongly recommends 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. Please note, even though Grants.gov allows you to attach any file format as part of your application, HHS/OASH restricts this practice and only accepts the file formats identified above. 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.

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 information in the application will not be forwarded for consideration.

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 <http://www.grants.gov>. You must search the downloadable application page by the Funding Opportunity Number or 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 Contacts below. See Section D.3 for requirements related to DUNS numbers and SAM registration.

G. 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. Project Merit, Contribution, and Evidence (30)

The application will be assessed based on the degree to which it:

- Justifies the project could meaningfully improve optimal health, across the reproductive lifespan, including preventing teen pregnancy and reducing STI rates; could meaningfully contribute to reducing health disparities compared to other available options; and adequately addresses contextual factors and assumptions that could impact the project's success.
- Provides data from formative evaluation of the intervention to justify that the intervention is necessary for the target population, supported by the target population, a good fit for the target population, and that the target population had a positive experience participating in the intervention.

- Demonstrates compelling, positive preliminary evidence for the intervention from formative evaluation, including effects on target outcomes.
- Justifies the research questions are necessary and meaningfully contributes useful and relevant information to the field; is aligned with the goals and purpose of the intervention.
- Demonstrates potential to scale the intervention and be replicated by others; commits to sustaining and improving the intervention; will disseminate results to stakeholders.

b. Evaluation Design (25)

The application will be assessed based on the degree to which it:

- Justifies the evaluation will assess the impact and implementation of the intervention, including how and why the intervention works.
- Proposes an RCT or QED rigorous evaluation design and proposes an efficacy or effectiveness study; includes implementation research; justifies why the method(s) selected have the most robust possible design that can be feasibly implemented.
- Demonstrates appropriate measures/instruments, data sources, data collection methods or existing data that align with the research questions, evaluation, intervention, and theory of change.
- Justifies a feasible proposed sample size, catchment area, and power that can detect an impact on the outcome(s) proposed; includes a sample size

that accounts for potential attrition, missing data, and other evaluation challenges and can detect a meaningful effect size.

- Includes a counterfactual that is different enough from the treatment condition to produce a meaningful test and allow for sufficient power.
- Demonstrates a credible evaluation structure and design that minimizes bias and addresses internal and external validity.

c. Readiness and Feasibility (20)

The application will be assessed based on the degree to which it:

- Demonstrates final, accessible, and available intervention materials and supporting materials or trainings (including any counterfactual programming, if applicable) that are already trauma-informed, medically accurate, age-appropriate, and user-centered; shows how the intervention has changed based on prior implementation, user feedback and formative evaluation results; and justifies the success of implementation(s) with formative evaluation data.
- Includes an evaluation that is ready to begin with sample recruitment plans, counterfactual group(s), assignment or formation plan for the counterfactual, data collection/dataset plan, participant tracking systems; demonstrates evaluation instruments have been piloted with the target population and/or administrative data would be accessible; could complete data collection for the full sample size before Dec. 2022; can reach a sample size large enough to power the evaluation and factors in attrition, missing data, other loss.

- Includes a description of all partners needed for the project (such as implementation sites, independent evaluator, program implementers, if applicable), and describes the status of forming and executing signed agreements with each partner.
- Demonstrates infrastructure is in place at the time of application to run the project; demonstrates the timeline is feasible within the three year project period and scope of the project; shows likelihood to complete all major activities within the timeline outlined.
- Demonstrates the ability to receive all needed IRB approvals by the start of funding as evidenced by a description of draft IRB submission materials and evaluator's documented history of obtaining IRB approvals.

d. Capacity and Management (15)

The application will be assessed based on the degree to which it:

- Clearly identifies the proposed project team (including applicant and all key partners); justifies organizational capacity of the project team to carry out the project.
- Justifies expertise and background of key evaluation staff (including the lead evaluator) for the project; demonstrates evaluation staff have: conducted high quality rigorous impact evaluations similar to the design proposed, worked with the proposed data sources including data collection or obtaining extant data, conducted similar data analyses; obtained IRB approvals for projects similar in scope; demonstrated

success in recruiting, retaining, consenting and surveying (if applicable) similar samples; and written peer-reviewed journal publications based on evaluation findings.

- Justifies expertise and background of key intervention staff for the project; demonstrates intervention staff have: implemented the intervention with high quality before; received necessary training for the intervention; has extensive history working with the target population.
- Has managed similar projects efficiently and successfully; presents a clear description of roles and management strategies; includes a logical, structured organizational chart for the project.
- Demonstrates a neutral evaluation process; includes evaluation staff who do not have a perceived or actual conflict of interest to carry out the evaluation.

e. Work Plan and Budget (10)

The application will be assessed based on the degree to which it:

- Includes a work plan, budget, and budget narrative that adequately supports the planned project.
- Includes a work plan, budget, and budget narrative that clearly aligns with expectations of the grant and is reasonable and realistic;
- Includes a work plan that includes project goals, SMART objectives with supporting activities to meet each objective, the person(s) responsible, timeline for completing activities, and the measures of success.

- Includes a budget and budget narrative that justifies the amount requested; budget and narrative are reasonable, cost-efficient, and clearly aligned with the proposed work plan.
- Includes a budget and budget narrative that allocates funding for engaging participants and stakeholders consistent with the proposed project.

2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. 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 G.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions 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.

In providing these recommendations, the Deputy Assistant Secretary for Population Affairs will take into consideration the following additional factor(s): representation of diverse interventions, representation of a range of populations disproportionately impacted by teen pregnancy, diversity of research questions.

3. Review of Risk Posed by Applicant

The HHS/OASH 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. OASH will use a risk-based approach and may consider any items such as the following:

- 1) Your financial stability;
- 2) Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;
- 3) 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;
- 4) Reports and findings from audits performed; and
- 5) 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, HHS/OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including level of funding if an award is made, are final and you may not appeal.

HHS/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 project period start date.

H. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

HHS/ OASH does not release information about individual applications during the review process. If you would like to track your application, please see instructions at <http://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 of the HHS/OASH OGM. If you are successful, you will receive this document via 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 project period, 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 HHS/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. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

1. 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, or other Department regulations and policies in effect at the time of the award.

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 <http://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 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.

2. Program Specific Terms and Conditions

Prior approval is required for change of time or replacement of Key Personnel. Key Personnel include staff with responsibility and oversight for the day-to-day management of the project, as well as the lead evaluator.

3. Closeout of Award

Upon expiration of your project period, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the Principal Investigator/ Project Director, we may elect to complete a unilateral closeout. (See F.3 Reporting below for closeout reporting requirements.) As a result, we may determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

4. 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.

5. **Non-Discrimination Requirements**

Pursuant to Federal civil rights laws, if you receive an award under this announcement you must not discriminate on the basis of race, color, national origin, disability, age, and in some cases sex and religion. The HHS Office for Civil Rights provides guidance for complying with civil rights laws that prohibit discrimination. <https://www.hhs.gov/civil-rights/index.html>.

HHS provides guidance to recipients of federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency. See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311, 47313 (HHS Office for Civil Rights, 2003, www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf) You must ensure your contractors and subrecipients also comply with federal civil rights laws.

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, 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. Compliance with the National CLAS Standards meets the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency.

6. **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.

7. Acknowledgement of Funding and HHS Rights to Materials and Data

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 publication (journal article, etc.) was supported by Award No. _____ from the Office of the Assistant Secretary of Health (OASH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OASH.

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.

8. Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104). For the full text of the award term, go to http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

9. 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 <http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/>

10. 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.

11. 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. You may find it online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Applicants 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 www.hhs.gov/about-research-participation.

12. 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 ori.hhs.gov/assurance-program.

13. Reporting

a. Performance Reports

You must submit performance 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), in the Grant Notes module.

You will also be required to submit a final performance report covering the entire project period 90 days after the end of the project period. You must submit the final report by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

b. Performance Measures

OPA expects all recipients to collect a common set of performance measures to assess project implementation. Depending upon the approach, unique measures may be included related to whether the project is observing intended outcomes. Recipients must collect all performance measures and report to OPA on a semi-annual basis (pending Paperwork Reduction Act clearance by OMB). Performance measures are submitted to OPA through the OPA Performance Measures website. Draft performance measures are available in Appendix C. Final performance measures will be provided to recipients during the first six months of funding.

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 project period 90 days after the end of the project period. You must submit FFRs via our grants management system (GrantSolutions.gov) FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note, at this time, these FFR reports are separate submissions via the Payment Management System. At this time, data is not transferable between the two systems and you will report twice on certain data elements.

d. Audits

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

e. Non-competing Continuation Applications and Awards

Each year of the approved project period, 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. HHS/OASH will award continuation funding based on availability of funds, satisfactory progress of the project, and grants management compliance, including timely reporting. Additionally, 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 (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 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 HHS/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 HHS/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.

I. CONTACTS

1. Administrative and Budgetary Requirements:

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

Roscoe Brunson

Office of Grants Management

1101 Wootton Parkway, Suite 100

Rockville, MD 20852

Phone: 240-453-8822

Email: roscoe.brunson@hhs.gov

2. Program Requirements

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

Tammy Bartasavich

Office of Population Affairs

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

Phone: 240-276-8119

Email: Tammy.Bartasavich@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: www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

J. 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).
- Assurances for Non-construction Programs (SF-424B).
- 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; Project Timeline; Organizational Chart; Visual Depiction; CVs/Resumes; MOUs/Agreements.

Diane Foley, MD, FAAP
Deputy Assistant Secretary, Office of Population Affairs

Date

APPENDIX A – GLOSSARY OF SELECTED TERMS AND DEFINITIONS

Adolescent Health: Think, Act, Grow® (TAG): TAG is a national call to action to improve adolescent health in the United States. The U.S. Department of Health and Human Services collaborated with a range of youth-serving professionals and youth themselves to create the following TAG five essential components of adolescent health: positive connections with supportive people; safe and secure places to live, work and play; access to high quality and teen friendly health care; opportunities to engage as learners, leaders, team members, and workers; and coordinated adolescent and family centered services.

Age appropriate - Assures that topics and themes are appropriate for the age group and other specific characteristics of the target audience. Age appropriate means it will be appropriate for the general developmental and social maturity of the targeted age group. The ability to cognitively understand a concept is not evidence that the concept is age appropriate.

Counterfactual - the comparison or control group(s) in the evaluation to provide a contrast to the treatment or intervention group.

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 if a study were not being conducted 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.

Formative Evaluation – Evaluation to test different elements of the intervention and implementation. This can occur while the program is still being developed. Primary goal of the formative evaluation is to develop, test, and learn about the intervention before rigorous or summative evaluation.

Health Equity - Health equity is achieved when every person has the opportunity to attain his, her, or their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances. Health inequities are reflected in

differences in length of life; quality of life; rates of disease, disability, and death; severity of disease; and access to treatment.

Impact Evaluation – Evaluations designed to measure the impact of an intervention on a specific outcome. Impact evaluation generate evidence of efficacy or effectiveness of a fully-developed intervention by providing estimates of the intervention’s ability to achieve its intended outcomes.

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, among others.

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 programs, models, components, products, approaches, and strategies being evaluated by the grant

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 information that leading professional organizations and agencies with relevant expertise in the field recognize as accurate, objective, and complete.

Optimal Health: Optimal health is a dynamic balance of physical, emotional, social, spiritual, and intellectual health. Lifestyle change can be facilitated through a combination of learning experiences that enhance awareness, increase motivation, and build skills and, most important, through the creation of opportunities that open access to environments that make positive health practices the easiest choice.

Project: All activities, including but not limited to intervention, implementation, evaluation, and research, described in the application, and funded by the grant or cooperative agreement.

Rigorous 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

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 on-going 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 the intervention.

Trauma-informed: A trauma-informed approach is one 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.

APPENDIX B - REFERENCES

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7. O'Donnell M.P. Definition of Health Promotion 2.0: Embracing Passion, Enhancing Motivation, Recognizing Dynamic Balance, and Creating Opportunities. *American Journal of Health Promotion*: September/October 2009, Vol. 24, No. 1, pp. iv-iv.
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https://www.acf.hhs.gov/sites/default/files/opre/acf_common_framework_for_research_and_evaluation_v02_a.pdf. Accessed November 26, 2019

9. CONSORT, Transparent Reporting of Trials. <http://www.consort-statement.org/>. Accessed November 26, 2019.
10. Transparent Reporting of Evaluations with Nonrandomized Designs, Centers for Disease Control and Prevention. <https://www.cdc.gov/trendstatement/index.html>. Accessed November 26, 2019.

APPENDIX C – PERFORMANCE MEASURES (DRAFT-SUBJECT TO CHANGE)

OMB No. 0990-0468

Expiration Date: 7/31/2022

General Information

1. Program model Name (curriculum, intervention, strategy) name(s)
2. Implementation Setting(s) (select one based on the primary location of the programming):
 - In school
 - Out-of-school time (on school campus)
 - Community-based programs
 - Juvenile Justice Centers
 - Out-of-Home Care
 - Clinic
 - Technology-Based project
3. State (select)
4. Urbanicity (select one for each section/class/group implemented):
 - Urban
 - Rural
 - Suburban

Reach and Demographics

These data are collected and entered for every participant in aggregate at the level of a class or group receiving the program or services together

Youth Served

5. For each group or class, enter the total number of youth participants that were served? _____
6. For each group or class, enter the total number of youth participants that were served, by gender:
 - Male _____
 - Female _____
 - Does not identify _____
 - Did not report _____
7. For each group or class, enter the total number of youth participants that were served, by age group:
 - ≤ 10 years _____
 - 11-12 years _____
 - 13-14 years _____
 - 15-16 years _____
 - 17-18 years _____

Did not report

8. For each group or class, enter the total number of program participants (youth ages 11-19) that were served, by grade level?

≤ Grade 6 _____
Grades 7- 8 _____
Grades 9 – 10 _____
Grades 11-12 _____
Not currently attending school _____
College student _____
Unknown Educational Status _____

9. For each group or class, enter the total number of program participants (youth ages 11-19) that were served, by race and ethnicity? [cross-tabulate individual reports]

Hispanic/Latinx, White
Hispanic/Latinx, Black
Hispanic/Latinx, Asian
Hispanic/Latinx, American Indian/Alaska Native
Hispanic/Latinx, Hawaiian/Pacific Islander
Hispanic/Latinx, Race not specified
Non-Hispanic/Latinx, White
Non-Hispanic/Latinx, Black
Non-Hispanic/Latinx, Asian
Non-Hispanic/Latinx, American Indian/Alaska Native
Non-Hispanic/Latinx, Hawaiian/Pacific Islander
Non-Hispanic/Latinx, Race not specified
Unreported Race and Ethnicity

Reach of other, non-youth program participants.

10. For each group or class, enter the total number of parent/guardians (of youth ages 11-18) that were served by the intervention? _____

11. For each group or class, enter the total number of youth-serving professionals (such as teachers, social workers, and other professions who work with youth ages 11-18) that were served by the intervention? _____

Fidelity and Quality

Fidelity and Quality Items reference to the TPP observation form, the TPP Fidelity Process Form, or the individual program model fidelity logs.

12. For each session of programming observed, what is the overall quality of programming (on scale of 1 – 5) [Uses the TPP Observation Form]

13. During the past six-month reporting period, how many sessions [meetings] of programming were observed by an independent observer for fidelity and quality? _____

14. How many sessions (meetings) were planned for each class or group of the program model/strategy/intervention? _____
15. How many sessions (meetings) were implemented for each class or group of the program model/strategy/intervention? _____
16. How many activities were planned for each class meeting observed? _____
17. How many activities were completed for each class meeting observed? _____
18. What is your project's total score on the fidelity process scale? [Refers to the TPP Fidelity Process Form] _____

Dosage

Dosage metrics are derived from attendance records, and are reported in aggregate for each class or group who received programming together.

19. How many youth received at least 75% of the overall program? _____
20. What was the average participant daily attendance for the class? _____
21. How long (in minutes) was each meeting of the program? _____

Training and Staffing

22. Number of facilitators (program implementers) planned to be hired initially (reported at the start of the project) _____
23. Number of facilitators actually hired during the 6 month reporting period (that is, the 6 months prior to reporting) _____
24. Number of facilitators trained during each 6 month reporting period _____
25. Number of facilitators retained within the project (during each 6 reporting period) _____

Partnerships

26. Enter the number of Implementation sites planned, as of the start of the grant (Year 1) _____
27. Of those implementation sites planned as of the start of the grant (Year 1) [Question 27], enter the Number of those sites with fully executed Memorandum of Understanding (MOU) in place as of this reporting deadline. _____
28. Enter the Number of new implementation sites (not planned, per question 27) with fully executed MOUs in place as of this reporting deadline. _____
29. Enter the Number of implementation sites retained as of this reporting deadline. _____

Dissemination

30. 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. _____

31. Please list the references for any published manuscripts published in the past year.

32. During the reporting period, where was information about the program presented? Write the number of times each presentation occurred.

- _____ National Conference/Event
- _____ Statewide Conference/Event
- _____ Local Meeting/Event
- _____ Other (explain)