



Office of the
Assistant Secretary
for Health

Office on Women's Health

Notice of Funding Opportunity:

**Addressing Eating Disorders in Adolescent Girls
and the COVID-19 Pandemic**

Opportunity Number: WH-AST-22-005

Application Due Date:

July 15, 2022 at 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

Office of the Assistant Secretary for Health, Office on Women's Health

FUNDING OPPORTUNITY TITLE

Addressing Eating Disorders in Adolescent Girls and the COVID-19 Pandemic

ACTION

Notice

ANNOUNCEMENT TYPE

Initial Competitive Grant

FUNDING OPPORTUNITY NUMBER

WH-AST-22-005

ASSISTANCE LISTING NUMBER AND PROGRAM:

93.088 Advancing System Improvements for Key Issues in Women's Health

DATES

Application Deadline: July 15, 2022 by 6:00 PM Eastern.

Technical Assistance: Webinar, May 25, 2022 at 1:00 PM Eastern.

EXECUTIVE SUMMARY

The Office on Women's Health (OWH) announces the availability of funds for Fiscal Year (FY) 2022 Grants under the authority of section 1703(a) of the Public Health Service (PHS) Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a).

This notice solicits applications to fund up to three (3) projects focusing on adolescent girls at risk for eating disorders exacerbated by the COVID-19 pandemic. Each project will identify, develop, and implement an evidence-based intervention(s) aimed at detecting and preventing eating disorders.

Each project must:

- Develop and implement an evidence-based intervention(s) to address modifiable risk factors, encourage behavior change, and improve health outcomes in response to challenges posed by the COVID-19 pandemic;

- Create partnerships that integrate physical and mental health aspects of eating disorders among care providers, nutritionists, and/or community organizations to address gaps in care exacerbated by the COVID-19 pandemic;
- Create developmentally appropriate education and outreach for adolescent girls at risk for eating disorders; and
- Plan for transition of a successful project to sustainability.

OWH intends to fund projects focusing on eating disorders. Each funded project will focus on at least one of the following: anorexia nervosa, bulimia, binge-eating disorder, and/or avoidant restrictive food intake disorder (ARFID). The target population for projects is adolescent girls. The projects will be expected to track and evaluate outcomes to assess success.

Applicants may be a public or private (profit or non-profit) entity. Examples are found in Section E.1.

OWH anticipates making up to 3 grant awards of up to \$500,000 each for the first year for a total of \$1,500,000 in FY2022. OWH anticipates project periods of up to three years awarded in annual budget periods. Recipients will be required to submit a non-competing continuation application for each budget period for the second and third years. OWH anticipates offering a competing continuation for a fourth year for the purpose of providing funding to support selected recipients as they transition projects to sustainability. Funding for the budget periods after the first year will be contingent upon availability of funding, satisfactory performance (including recipient progress towards meeting stated project milestones and goals, timely submission of required reports, and compliance with all grant terms and conditions), and the best interests of the government.

HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that their application complies with all requirements and instructions.

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FUNDING OPPORTUNITY DETAILS

A. DATES

1. Application Deadline

Your application is due July 15, 2022 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, Grants and Acquisitions Management (GAM) Division, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS). To obtain an exemption, you must request one via email from GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline.

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

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

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

To ensure adequate time to submit your application successfully, OASH recommends that you register as early as possible in Grants.gov because the registration process can take up to one month. You must register an authorizing official for your organization. OASH does not determine your organization's authorizing official; your organization makes that designation. For

information on registering for Grants.gov, refer to <https://grants.gov> or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

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

2. Technical Assistance

We will provide a technical assistance webinar for potential applicants on May 25, 2022 at 1:00 PM Eastern Time. Registration details will be posted at <https://womenshealth.gov>.

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 (OASH), Office on Women's Health (OWH) announces the availability of funds for Fiscal Year (FY) 2022 under the authority of section 1703(a) of the PHS Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a). The primary focus of OASH 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, OWH provides national leadership and coordination to improve the health of women and girls through policy, education, and innovative programs. OWH advances and coordinates a comprehensive women's health agenda across HHS and works to develop and expand innovative approaches to advance the field of women's and girls' health.

1. Background

The COVID-19 pandemic has impacted individuals living with or at risk of eating disorders. Eating disorders are serious and often fatal illnesses associated with severe disturbances in people's eating behaviors and related thoughts and emotions (National Institute of Mental Health, 2021). Projects funded through this initiative will focus on one or more of the following eating disorders:

- (a) anorexia nervosa, a condition where people avoid food, severely restrict food, or eat very small quantities of only certain foods;
- (b) bulimia, a condition where people have recurrent and frequent episodes of eating unusually large amounts of food and feeling a lack of control over these episodes followed by a type of behavior that compensates for the binge, such as purging;

- (c) binge-eating disorder, a condition where people lose control over their eating and have reoccurring episodes of eating unusually large amounts of food; and/or
- (d) avoidant restrictive food intake disorder (ARFID), previously known as selective eating disorder, a condition where people limit the amount or type of food eaten resulting in not eating enough calories to grow or to maintain basic body function (National Institute of Mental Health, 2021).

Eating disorders became the fifth most prominent mental health condition as of August 2020 (Katzman, 2021). In addition, a recent review of 70 research articles revealed eating disorder symptom severity and incidence of probable diagnoses appear to be elevated during the COVID-19 pandemic (Linardon, Messer, Rodgers, & Fuller-Tyszkiewicz, 2022). The upswing comes at a time when barriers to treatment have increased during the pandemic, making access to care difficult (Reed & Ort, 2021). Additionally, researchers have noted that many young people with eating disorders dismiss the significance of their symptoms or do not seek professional help for their symptoms or concerns (Schlegl, Maier, Meule, & Voderholzer, 2020).

The average age of onset is between 12 and 25 years, making adolescence a high-risk time for developing an eating disorder (Volpe, et al., 2016). However, less than 20% of college students with eating disorders report receiving treatment (Eisenberg, Nicklett, Roeder, & Kirz, 2011). Collaborative touchpoints with members of multidisciplinary healthcare teams and innovative modes of outreach to individuals with eating disorders may help to reach individuals currently not receiving any treatment (Heafala, Ball, Rayner, & Mitchell, 2021) (Kazdin, Fitzsimmons-Craft, & Wilfley, 2017). Moreover, those who receive care may benefit from collaboration among care providers across specialties, yet care is not often integrated, which may hinder successful interventions (Da Luz, Hay, Touyz, & Sainsbury, 2018).

The COVID-19 pandemic has increased the risk of and barriers to care for eating disorders (Vuillier, May, Greville-Harris, Surman, & Moseley, 2021). Patient referrals to eating disorder treatment centers increased 30-40% (Katzman, 2021). The demand for treatment may be greater than has been reported (Otto, et al., 2021). According to a recent study, nearly 80% of those identified with an existing eating disorder had concerns that their condition may regress due to a lack of structure during the pandemic (Spigel, et al., 2021). Researchers found disrupted routines, requirements for physical and social distancing, greater exposure to environmental triggers, and difficulties regulating emotion as possible reasons for worsening symptoms. Some researchers have noted anxiety and depression are on the rise for many teens because of the pandemic, which can also impact symptoms (Konstantinovsky, 2020).

In addition, during the pandemic, time spent on and engagement with social media sites increased for many adolescents. Social media has been associated with body dissatisfaction, drive for thinness, and low self-esteem (Saunders & Eaton, 2018) (Zemlyanskaya, Valente, & Syurina, 2021). Young women who are already suffering from or in treatment for an eating disorder are much more susceptible to the influence and pressures of social media (Zhang, Liu, Li, & Chung, 2021).

This funding opportunity seeks projects with evidence-based intervention(s) to address these conditions exacerbated by the COVID-19 pandemic. Targeted efforts will require an understanding of pandemic-related stressors and potential barriers to early diagnosis. Fostering partnerships among key stakeholders will be critical to support the development of evidence-based intervention(s).

2. Expectations for Funded Projects

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

a. Develop and implement evidence-based intervention(s)

To improve detection and prevention of eating disorders, we expect recipients to develop and implement evidence-based intervention(s) to address modifiable risk factors, encourage behavior change, and improve health outcomes in response to challenges posed by the COVID-19 pandemic. Intervention(s) should focus on detecting and preventing eating disorders in adolescent girls at risk of developing an eating disorder. Evidence-based intervention(s) should address the contributing factors of social isolation, loneliness, or social restrictions. These contributing factors were uniquely heightened during the COVID-19 pandemic among adolescent girls.

We encourage recipients to include approaches and evidence-based intervention(s) that address health equity related to eating disorders. Recipients should identify and track outcomes to demonstrate improvements in early detection and prevention of eating disorders among at-risk adolescent girls. We expect recipients to both quantitatively and qualitatively evaluate their projects in improving detection and prevention of eating disorders. Recipients should demonstrate how their intervention(s) has improved the early detection and prevention of eating disorders and methods used for assessment of the eating disorder(s). Additionally, recipients should disseminate outcomes of the intervention(s) both quantitatively and qualitatively.

b. Create partnerships to address gaps in care

We expect recipients to evaluate the gaps in care for adolescent girls with eating disorders and develop partnerships that integrate physical and mental health aspects of eating disorders among care providers, nutritionists, and/or community organizations. Recipients should engage these partners and stakeholders to participate in the development and implementation of intervention(s) to address the identified gaps in care. We expect recipients to engage partners throughout the intervention(s) to address modifiable risk factors, encourage behavior change, improve health outcomes, and create developmentally appropriate education and outreach for adolescent girls at risk for eating disorders. We expect partnership(s) to be documented as described in Section F.3.c.2.

c. Create developmentally appropriate education and outreach

OWH expects recipients to engage adolescent girls at risk for developing or who currently experience an eating disorder through developmentally appropriate innovative education and outreach. For example, recipients may consider content specifically tailored to post-pandemic adolescents for social media platforms where there is an increased risk of developing eating disorders or through curricula, manuals, videos, apps, or other evidence-based approaches.

We expect recipients to incorporate the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards). Recipients should, as appropriate to the intervention(s), provide effective, equitable, understandable, and respectful quality care and services responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs. Recipients should offer language assistance to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all health care and services; inform all individuals of the availability of language assistance services clearly and in their preferred language, verbally and in writing; ensure the competence of individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided; and provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.

d. Disparity Impact Statement

Recipients are expected to develop a disparity impact statement (DIS) during the project period using local data to identify populations at highest risk for health disparities relative to this initiative.¹ A DIS refers to the demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities. The DIS will provide the measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and overarching goal of advancing health equity. Project activities must comply with the non-discrimination requirements described in Section H.6.

Below are available HHS resources:

- CMS.gov: Quality Improvement & Interventions: Disparity Impact Statement (<https://www.cms.gov/About-CMS/Agency-Information/OMH/resource-center/hcps-and-researchers/quality-improvements-and-interventions>)

¹ Applicants may choose to use the Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Social Vulnerability Index (SVI) [<https://www.atsdr.cdc.gov/placeandhealth/svi/index.html>], or other local data tools, in developing disparity impact statements.

- SAMHSA.gov: Disparity Impact Statement
(<https://www.samhsa.gov/grants/grants-management/disparity-impact-statement>)
- OMH Disparity Impact Strategy
<https://www.minorityhealth.hhs.gov/omh/content.aspx?ID=22540>

Additional information and links to resources are available in Section K.4.

e. Plan for transition of a successful project to sustainability

We expect recipients to plan for and work toward sustainability of successful evidence-based intervention(s) beyond the end of the funded project. Recipients should begin to develop a plan for sustainability by the end of the second year. We expect the plan to identify key individuals and/or organization(s) whose support will be required to sustain activities; financial and staff resources needed; and existing collaborative partnerships with organizations that might support continuation of the project after the final budget period expires. In the third year, successful projects will have the option to compete for one more year of funding to aid in the transition to sustainability.

C. AUTHORITY

Section 1703(a) of the PHS Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a)

D. FEDERAL AWARD INFORMATION

The Office on Women's Health intends to make funds available for competing grant awards. We will fund awards in annual increments (budget periods) and generally for a period of performance up to three (3) years with an optional competitive fourth year, although we may approve shorter periods of performance. Recipients will be required to submit a non-competing continuation application for each budget period for the second and third years. We anticipate offering a competing continuation for a fourth year for the purpose of providing funding to support selected recipients as they transition projects to sustainability.

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, adequate stewardship of Federal funds, and the best interests of the Government.

Award Information

Estimated Federal Funds Available: \$ 1,500,000

Anticipated Number of Awards: 3

Award Ceiling (Federal Funds including indirect costs): \$ 500,000 per budget period

Award Floor (Federal Funds including indirect costs): \$ 300,000 per budget period

Anticipated Start Date: September 15, 2022

Estimated Period of Performance: Not to exceed 3 year(s) with an optional competitive fourth year for transition to sustainability

Anticipated Initial Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted:

Electronic via Grants.gov ONLY unless an exemption is granted

E. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private (profit or nonprofit) entity located in a State (which includes one of the 50 United States, District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands) is eligible to apply for an award under this announcement. Community-based organizations, faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply. Examples of eligible Organizations include:

- State Governments
- U.S. territories
- County Governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public Housing authorities/Indian housing authorities

- Native American tribal organizations (other than federally recognized tribal governments)
- Nonprofits having 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
- Private institutions of higher education
- For profit organizations, including small businesses.

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget. If you voluntarily include cost sharing in your application, you must include in your budget narrative a non-federal sources justification as described in Section F.3.b.1.t. Voluntary cost sharing is not expected for research applications. During the merit review of an application, cost sharing will only be considered in the overall review of the adequacy of the total proposed budget (Federal and non-Federal share) to support the project proposed. Applications including cost sharing or matching, whether required or voluntary, that result in an award will include the cost sharing or matching commitment on the notice of award at the level proposed in the application. See Section F.3.b.1.s. Any change in the responsibility to provide cost sharing or matching at that level will require prior approval of the grants management officer.

3. Other – Application Responsiveness Criteria

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

- You must identify in the first paragraph of your project narrative at least one of the conditions (i.e., anorexia nervosa, bulimia, binge-eating disorder, and/or ARFID) that is the focus of your project. You may select up to all four of the conditions, but you must identify at least one of the four conditions to be responsive.

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 <https://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/GAM 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 application must be submitted in the English language and must be in the terms of U.S. dollars (45 C.F.R. § 75.111(a)).
- (f) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.
- (g) Your Project Narrative must not exceed **25** 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).
- (h) Your total application, including the Project Narrative plus Appendices, must not exceed **55** pages. NOTE: items listed in "(g)" immediately above do not count toward total page limit.
- (i) Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.
- (j) Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.
- (k) Your application must meet the Application Responsiveness Criteria outlined above.
- (l) If your application includes cost sharing (voluntary or required), you must include in your budget narrative a non-federal sources justification.

F. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

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

OASH Grants and Acquisitions Management Division

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a. Application Format

Your application must be prepared using the forms and information provided in the online application package. This includes but is not limited to: SF-424 Application for Federal Assistance; SF-424A Budget Information for Non-Construction Programs; SF-424B Assurances for Non-Construction Programs.; SF-LLL Disclosure of Lobbying Activities; and Project Abstract Summary.

We encourage individuals to use their full name (first, middle, last) on the Standard Forms and other documents such as resumes and curriculum vitae to distinguish them for verification in the System for Award Management exclusion records. Delays may result in award processing if full names are not provided. NOTE: only one Project Director/Principal Investigator will be named on any resulting award. You should clearly identify the individual in that role in your application.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section E.4. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria.

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, 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 F.3.c, 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/biosketches, 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.

d. Budget Narrative Format

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

3. Application Content

Successful applications will contain the following information:

a. Project Narrative Content

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

NOTE: You must identify in the first paragraph of your project narrative **at least one of the conditions (anorexia nervosa, bulimia, binge-eating disorder, and/or ARFID) that is the focus of your project.** You may select up to all four of the conditions, but you must identify at least one of the four conditions to be responsive.

1) Statement of Need

You should describe in this section, in both quantitative and qualitative terms, the nature and scope of the specific and particular need the project is designed to address, and the condition(s) of focus. You should include in your description the impact of the COVID-19 pandemic on your target population. Also describe any unique circumstances the pandemic created for adolescent girls at risk or diagnosed with the condition(s) of focus.

Describe the population(s) of focus, including demographic characteristics, and the geographic location. You should detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified.

You should describe how your proposed intervention(s) will engage underserved and disadvantaged populations, including racial/ethnic minorities, limited-English speaking populations, and persons with disabilities. Note, your project activities may not involve the selection or exclusion of participants based on race/ethnicity. Additionally, this section should outline who you consider vested stakeholders in the project (for example community-based organizations and/or hospitals), how they were or will be identified, and how they will be meaningfully engaged in the project. You should provide memoranda of agreement and/or letters of commitment as described below in the appendices section.

We recommend that you focus your statement of need on the specific aspects of the history and policy considerations bearing on the program area and existing literature with a focus on high quality evidence including randomized controlled trials, cohort studies, case control studies, and if necessary, case series from the primary literature. Avoid providing a broad or sweeping historical overview that is not directly related to the proposed intervention(s) and activities.

2) Goals, Objectives, and Outcomes

This section should start with the specific question or hypothesis you will address, the rationale for the question or hypothesis, and how your project's proposed goal(s) and major objectives will address this question. You should provide a realistic and clear timetable for the project and intervention(s) and a rationale that these timelines are achievable. Describe your objectives in the SMART format (Specific, Measurable, Achievable, Relevant and Time-Oriented). For example, "By the end of month one, create a plan for developing the evidence-based intervention."

You should clearly state the expected outcome(s) that will result from your project after you: (1) Develop and implement evidence-based intervention(s) to address modifiable risk factors, encourage behavior change, and improve health outcomes in response to challenges posed by the COVID-19 pandemic; (2) Create partnerships that integrate physical and mental health aspects of eating disorders among care providers, nutritionists, and/or community organizations to address gaps in care exacerbated by the COVID-19 pandemic; (3) Create developmentally appropriate

education and outreach for adolescent girls at risk for eating disorders; and (4) Plan for transition of a successful project to sustainability.

HHS/OASH will not fund any project that does not include measurable outcomes. In addition, you should describe how you envision the project will benefit the field at large.

A measurable outcome is an observable end-result that describes how a particular intervention(s) benefits project participants. It demonstrates the “impact” of the intervention(s). For example, a change in a client’s financial, health, and/or functional status; mental well-being; knowledge; skill; attitude; awareness; or behavior. It can also describe a change in the degree to which participants exercise choice over the types of services they receive, or whether they are satisfied with the way a service is delivered. Additional examples include: a change in the responsiveness or cost-effectiveness of a service delivery system; a new model of support or care that can be replicated; new knowledge; a measurable increase in community awareness; or a measurable increase in persons receiving services. A measurable outcome is not a measurable output, such as: the number of clients served; the number of training sessions held; or the number of service units provided without demonstration that this improved a measurable clinical outcome.

3) Proposed Approach

You should provide a clear and concise description of the intervention(s) you are proposing to use to address the need you identified in your statement of need. You should explain the rationale for using a particular intervention(s) and to present a clear connection between identified system gaps and needs and your proposed activities. Your proposal should detail the nature of the activities to be undertaken, how they address identified issues, how they will account for post-pandemic risk factors, and how they will assist in achieving the overall project goals and objectives. You should clarify why these specific activities were selected (e.g., has this approach been successful in other settings or does the research suggest this direction). You should describe how your intervention(s) is evidence-based. For an intervention(s) to be evidence-based, it must be informed by research and utilize effective methodology.

Your proposal should demonstrate how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and/or disseminate information and products. You should provide specifics about the intervention(s), expected outcomes, and barriers for all anticipated years of the award.

Your proposed project should incorporate the National CLAS Standards (See Section K.3). In particular, you should demonstrate how you will provide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs. You should also demonstrate how you will: offer language assistance to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all health care and services; inform all individuals of the availability of language assistance services clearly and in their preferred language, verbally and in writing; ensure the competence of

individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided; and provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.

In reference to the Work Plan that you will separately submit as a table or chart in your Appendices (Section F.3.c), describe your implementation of the above approach over the three-year project. Your proposed approach must include, at a minimum, a description of how you will:

- Develop and implement evidence-based intervention(s) to address modifiable risk factors, encourage behavior change, and improve health outcomes in response to challenges posed by the COVID-19 pandemic; (See Section B.2.a)
- Create partnerships that integrate physical and mental health aspects of eating disorders among care providers, nutritionists, and/or community organizations to address gaps in care exacerbated by the COVID-19 pandemic; (see Section B.2.b)
- Create developmentally appropriate education and outreach for adolescent girls at risk for eating disorders; (see Section B.2.c) and
- Plan for transition of a successful project to sustainability (see Section B.2.e).

4) Evaluation

You should describe the methods you will use to evaluate if the proposed intervention(s) achieves its measurable outcome(s) and assess and evaluate the impact of the activities you propose, including challenges posed by the COVID-19 pandemic. You should describe how you will measure and report on the outcomes of the project, including how the expectation for independence of the evaluator will be met. You should describe both the quantitative and qualitative tools and techniques that you will employ to measure the outcome(s) and how you will identify and document the lessons learned. Your evaluation plan should describe your approach for a robust statistical analysis.

Suggested resources for developing an Evaluation Plan include:
https://www.cdc.gov/dhbsp/evaluation_resources/tips-training.htm and
<https://www.cdc.gov/std/program/pupestd/types%20of%20evaluation.pdf>

5) Organizational Capability

You should describe your organization's capability to successfully implement the proposed project. You should describe how your organization (or the particular division of a larger organization which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Your description should cover your capabilities not included elsewhere in the project narrative, including demonstrated capacity and capability to work with the population of focus, any current or previous relevant experience, and/or the record of the

project team in preparing cogent and useful reports, publications, and other products. You should demonstrate relevant, appropriate experience and educational background for proposed positions on the project, as supported by the curricula vitae, résumés, or bio sketches for key personnel. If appropriate, include an organizational chart in your Appendices showing the relationship of the project to the current organization (See Section F.3.c).

You should clearly delineate the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's objectives and outcomes. You should specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and HHS/OASH. You should also describe the approach that will be used to monitor and track progress on the project's tasks and objectives. You should clearly identify the individual who will serve as the Principal Investigator/Project Director (PI/PD) and that individual's qualifications, competing time commitments, and related ongoing projects. HHS/OASH expects that, throughout the award period, the PI/PD will have involvement in, and substantial knowledge about, all aspects of the project.

You should describe the collaborative partnership(s) which will support project activities. You should describe the role and makeup of partners intended to be involved in completing specific tasks. Describe the anticipated level of effort and responsibilities of each partner in completing programmatic activities.

Also include information about any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals.

6) Dissemination

You should describe the method you will use to disseminate the project's results and findings in a timely manner and in easily understandable formats to the population served, the general public, and other parties who might be interested in using the results of the project. This may include but is not limited to peer reviewed journals. HHS/OASH may publish (including on a website), all appropriate findings and products (See Section H.9). You should propose other, innovative approaches to informing parties who might be interested in using the results of your project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project.

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 period** in the object class budget in box 6 of the SF-424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget period.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. 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. **Subrecipient/contract and consultant activities must be described in sufficient detail to describe accurately the project effort that each will conduct.**

1) Object Class Descriptions and Required Justifications

(a) Personnel Description

Costs of staff salaries and wages, excluding benefits.

(b) Personnel Justification

Clearly identify the 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 F.7.b 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 entity (including non-employee individuals), you must provide a detailed budget and budget narrative for each subrecipient/contractor, by title/name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be 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 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 period of performance for fully-funded awards, even if the justification by budget period, or by period of performance for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports.

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

awards). **If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review.**

2) Plan for Recipient Oversight of Federal Award Funds

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

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

If your internal controls are available online, it is recommended that you provide the link as part of your plan in the budget narrative. We have also included supplementary information in Section K.1, which contains questions applicants may find useful in considering their Recipient Plans for Oversight of Federal Funds.

c. Appendices

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

1) Work Plan

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the period of performance. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year,

action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. A suggested Work Plan Template is included in Section K.2.

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

If available at the time of submission, signed MOAs or signed LOCs may be submitted for each partner (or one signed MOA with all partners) and include specific roles, responsibilities, resources, and contributions of partner(s) to the project. If you are unable to submit signed MOAs, you should submit an unsigned MOA(s).

Signed LOCs must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the LOC.

Fully-executed MOAs may be required within the first 30 days following the start of the project period of any award made under this announcement.

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

3) Organizational Chart

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

4) Curriculum Vitae/Résumés/Biosketches for Key Project Personnel

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

5) References Cited

You should include your references cited in your project narrative as an appendix. You may use any standard format that you choose as long as it will clearly lead the reader to your source of the information or data.

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

On April 4, 2022, the federal government completed its transition from using the nine-digit DUNS number as the official unique entity identifier to the twelve-digit UEI(SAM) number. The UEI(SAM) is required for submission of applications. You may find additional information about the transition for both existing and new SAM registrants at https://www.fsd.gov/gsafsd_sp?id=gsafsd_kb_articles&sys_id=e31c534f1b40c1103565ed3ce54bcbce.

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

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/gsafsd_sp?sys_kb_id=8cfe46491b1cb8909ac5ddb6bc4bcbbb&id=kb_article_view&sysparm_rank=1&sysparm_tsqueryId=c6131c131bdcf0d0a7d7da49bc4bcb1a.

A quick start guide for registrants is available at https://www.fsd.gov/sys_attachment.do?sys_id=80f49f211bdcfc909ac5ddb6bc4bcb76. 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://www.fsd.gov/sys_attachment.do?sys_id=d08b64ab1b4434109ac5ddb6bc4bcbbc.

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

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/UEI 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 <https://grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

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

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>.

a. 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.

b. Salary Rate Limitation:

Each year’s appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2022, the Executive Level II salary is \$203,700. 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., 0.5 FTE	
Direct salary (\$350,000 x 0.5)	\$175,000
Fringe (25% of salary)	\$43,750
Total	\$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full-time salary <i>adjusted</i> to Executive Level II: \$203,700 with 50% of time devoted to the project	
Direct salary (\$203,700 x 0.5)	\$101,850
Fringe (25% of salary)	\$25,462.50
Total amount allowed	\$127,312.50

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 <https://grants.gov>.

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

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

We strongly recommend that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission, you may prevent any unintentional formatting that might occur with submission of an editable document. Please note, although Grants.gov allows you to attach any file format as part of your application, we restrict this practice and only accept the file formats identified above. 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 <https://grants.gov>. You must search the downloadable application page by the Opportunity Number or Assistance Listing (formerly CFDA) number, both of which can be found on page 1 of this funding opportunity announcement.

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

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

See Section F.4 for requirements related to DUNS/UEI numbers and SAM registration.

c. Program-Specific Requirements

There are no program specific requirements.

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. Statement of Need **(5 points)**

The degree to which the applicant has:

- Identified and clearly defined the need and contributing factors to the need, including COVID-19 pandemic-related factors, that will be addressed by the project activities using high-quality evidence, including randomized controlled trials, cohort studies, case-control studies, and, if necessary, case series from the primary literature, and policy considerations bearing on the project area.
- Comprehensively described the population(s) of focus, including demographic characteristics and the geographic area of focus, using recent, local, and disaggregated data wherever possible. Project activities may not involve the selection or exclusion of participants based on race/ethnicity.
- Described the connection between the population of focus and the identified conditions as appropriate.
- Described how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified.

b. Goals, Objectives, and Outcomes **(15 points)**

The degree to which the applicant:

- Demonstrated a strong and clear alignment of goals, objectives, and measurable outcomes with the project's purpose, expectations, and the applicant's statement of need, including response to challenges posed by the COVID-19 pandemic.
- Described the question or hypothesis to be tested, and the expected improvements following the intervention(s) described.

- Described major objectives that outline specific, measurable steps along with a timeline to achieve stated goal(s). Objectives are Specific, Measurable, Achievable, Relevant, and Time-Oriented (SMART).
- Provided a realistic and clear timetable for the project and intervention(s) and a compelling rationale for achieving these timelines.

c. **Proposed Approach (25 points)**

The degree to which the applicant:

- Provided a clear and concise work plan describing the intervention(s) focusing on anorexia nervosa, bulimia, binge-eating disorder, and/or avoidant restrictive food intake disorder (ARFID).
- Described an intervention(s) that is evidence-based. (For an intervention to be evidence-based, it must be informed by research and utilize effective methodology.)
- Explained the rationale for using a particular intervention(s) and presented a clear connection between identified issues and proposed activities.
- Detailed the plan for addressing the identified needs, the nature of the activities to be undertaken, how the activities address the identified needs, including COVID-19 pandemic-related needs, and how they will assist in achieving the overall project goals and objectives.
- Clarified why these specific activities were selected (i.e., Has this approach been successful in other settings? Does the research suggest this direction?).
- Described an approach to creating effective developmentally appropriate education and outreach materials for post-pandemic adolescent girls at risk for eating disorders. The approach involves print, multimedia materials, and signage in the languages commonly used by the populations of focus that are easy-to-understand.
- Demonstrated how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and/or disseminate information and products.
- Provided specifics about the intervention(s) linked to expected outcomes and barriers for all anticipated years of the award.
- Provided sufficient detail on how the project will incorporate effective, equitable, understandable, and respectful quality care and services that are

responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

- Detailed how the project will inform individuals of the availability of language assistance services and provided an adequate description of language assistance to be provided to individuals who have limited English proficiency and/or other communication needs, at no cost to them.

d. Evaluation (**20 points**)

The degree to which the applicant:

- Described the methods this project will use to evaluate whether the proposed intervention(s) achieves its measurable, quantitative outcome(s) and assesses and evaluates the impact of proposed activities.
- Described how outcomes of the project will be measured and reported, including a description of both quantitative and qualitative tools and techniques this project will employ to measure the outcome(s) and how lessons learned will be identified and documented.
- Described how the methods and interventions will assess any unique COVID-19 pandemic-related factors exacerbating eating disorder detection and prevention.
- Included a robust statistical analysis component in the evaluation plan.

e. Organizational Capability (**20 points**)

The degree to which the applicant:

- Demonstrated the organization's capability and readiness to implement the proposed project to achieve the proposed outcomes.
- Demonstrated a capacity and capability to work with the population of focus.
- Demonstrated a capacity and capability to work collaboratively with partner(s) as appropriate to meet the project goals.
- Demonstrated relevant, appropriate experience and educational background for proposed positions on the project as supported by the curricula vitae, résumés, or bio sketches for Key Personnel.
- Described the relationships among project personnel in the applicant organization with accountability for project activities in the Organizational chart.

- Described the role and makeup of potential subrecipients or partners intended to be involved in completing specific tasks and identified the level of effort each subrecipient is anticipated to provide in completing programmatic activities.

f. **Dissemination (10 points)**

The degree to which the applicant:

- Described the method(s) this project will use to disseminate results and findings in a timely manner and in easily understandable formats to the population served, the general public, and/or other parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project.

g. **Budget (5 points)**

- The extent to which the proposed budget adequately supports proposed activities, including how the total amount requested was determined; is detailed, reasonable, adequate, cost efficient, and aligned with the proposed technical approach.

2. Review and Selection Process

Each 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 rate 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 Women's Health will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. No award decision is final until a Notice of Award is issued by the Grants Management Officer.

In providing these recommendations the Deputy Assistant Secretary for Women's Health will take into consideration the following additional factor(s):

- Equitable geographic distribution.

3. Review of Risk Posed by Applicant

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

- a. Your financial stability;
- b. Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;
- c. History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- d. Reports and findings from audits performed; and
- e. Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

If we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 C.F.R. § 75.205(a)(2), we

must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must “demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics.” 45 C.F.R. § 75.205(a)(2); see also 45 C.F.R. §75.212 for additional information.

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

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

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

H. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

We do not release information about individual applications during the review process. If you would like to track your application, please see instructions at <https://www.grants.gov/web/grants/applicants/track-my-application.html>. The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH GAM. If you are successful, you will receive this document via a system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

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

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. 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.

2. Administrative and National Policy Requirements

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

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsggps107.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.

Note that the termination provisions located at 45 C.F.R. § 75.372 apply to all HHS awards. No additional termination provisions apply unless otherwise noted.

3. Program Specific Terms and Conditions

a. Disparity Impact Statement

Successful applicants may be expected to develop a disparity impact statement using local data to identify populations at highest risk for health disparities and low health literacy.

Additional information and links to resources are available in Section K.4.

4. Closeout of Award

Upon expiration of your period of performance, 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 must complete a unilateral closeout with the information available to us. (See H.16 Reporting below for closeout reporting requirements.) If you do not submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). As a result, we may also determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

5. Lobbying Prohibitions

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

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

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

6. Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals. See <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

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

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, <https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf>), provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. For

further guidance on providing culturally and linguistically appropriate services, you should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

7. Smoke- and Tobacco-free Workplace

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

8. Acknowledgement of Funding

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

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

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

Recipients must also include a disclaimer stating the following

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

9. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 C.F.R. § 75.322(b), HHS reserves a royalty-

free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 C.F.R. § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Trafficking in Persons

Awards issued under this 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) (See <https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm>).

11. Efficient Spending

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

12. Whistleblower Protection

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

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

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

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

telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

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

14. 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 <https://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 <https://www.hhs.gov/about-research-participation>.

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

15. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has

written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at <https://ori.hhs.gov/assurance-program>.

16. Reporting

a. Performance Reports

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

You will also be required to submit a final performance report covering the entire period of performance 120 days after the end of the period of performance. You must submit the final report by upload to our grants management system (GrantSolutions.gov).

b. Performance Measures

At the end of each reporting period, you should be able to:

- Describe accomplishments and progress toward project purpose/strategies/intervention(s) and quantify measurable outcomes as defined in the Work Plan.
- Summarize the status of the project's staffing situation.
- Describe the role and activities of each partnering organization.
- Describe accomplishments, current or anticipated problems, changes and progress on the evaluation plan.

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire period of performance 120 days after the end of the period

of performance. You must submit FFRs via HHS Payment Management System (PMS) (<https://pms.psc.gov>). Quarterly cash reporting via PMS on the FFR is also required.

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

d. Audits

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

e. Non-competing Continuation Applications and Awards

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

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

f. FFATA and FSRS Reporting

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

g. Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings

described in paragraph A.2 of Appendix XII to 45 C.F.R. part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 C.F.R. part 75.

h. Other Required Notifications

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

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

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

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

I. CONTACTS

1. Administrative and Budgetary Requirements:

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

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

2. Program Requirements

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

Linda Stella
200 Independence Avenue, S.W.
Washington, D.C. 20201
Phone: 202-690-7650
Email: linda.stella@hhs.gov

3. Electronic Submission Requirements

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

GRANTS.GOV Applicant Support
Website: <https://www.grants.gov>
Phone: 1-800-518-4726
Email: support@grants.gov

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
 - Memoranda of Agreement (MOAs) and/or Letters of Commitment (LOCs)
 - Organizational Chart
 - Curriculum Vitae/Resumes
 - References Cited

Dorothy A.
Fink -S

Digitally signed by Dorothy
A. Fink -S
Date: 2022.05.10 16:18:10
-04'00'

Dorothy Fink, MD
Deputy Assistant Secretary for Women's Health
Director, Office on Women's Health

Date

K. SUPPLEMENTARY MATERIALS

1. Considerations in Recipient Plans for Oversight of Federal Funds

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

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

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?
- Are specific officials designated to approve payrolls and other major transactions
- Does the time and accounting system track effort by cost objective?
- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?
- Do the procedures for cash receipts and disbursements include:
 - Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?
 - Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
 - All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?
 - Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

2. EXAMPLE WORK PLAN TEMPLATE

Sept. 15, 2022 – Sept. 14, 2023

Recipient Name _____ Funds Requested _____

<i>Goal 1:</i>		
<i>SMART Objective 1:</i>		
Measurable Outcomes for Objective 1: a. b. c.		
<i>Activities</i> in support of Objective 1: a. b. c.	Person/agency responsible for <i>Accomplishing Activities.</i> a. b. c.	<i>Activity Timeline.</i> a. b. c.

Protection and Affordable Care Act (Pub. L. 111–148) and administered by the Office of Adolescent Health (OAH). PAF provides funding to States and Tribes to provide expectant and parenting teens, women, fathers and their families with a seamless network of supportive services to help them complete high school or postsecondary degrees and gain access to health care, child care, family housing, and other critical supports. The Act appropriates \$25 million for each of fiscal years 2010 through 2019, and in August 2013, OAH awarded the first grants to 17 entities for up to four years. Grantees may use PAF grants to carry out activities in any of the following four *implementation categories*: (1) Support pregnant and parenting student services at institutions of higher education (IHE); (2) Support pregnant and parenting teens at high schools and community service centers; (3) Improve services for pregnant women who are victims of domestic violence, sexual violence, sexual assault, and stalking; and (4) Increase public awareness and education efforts about services available to pregnant and parenting teens and women.

This request is for a 3-year approval of the collection of PAF performance data. This is an annual reporting requirement of all PAF grantees. The reporting requirement varies according to the type(s) of activities implemented by each grantee. All PAF grantees are required to report a standard set of data elements that capture the demographic and social characteristics of the individuals served (“participants”) and the number and types of organizations that participate in implementing the project. In addition, grantees are required to report data for a set of measures defined for each implementation category.

Need and Proposed Use of the Information: The collection of annual performance data is important to OAH because it will provide OAH leadership and PAF program administrators with data needed to administer the PAF program and manage PAF awards and projects, including information to assess beneficiary characteristics; measure and monitor project implementation, outputs, and outcomes; and comply with reporting requirements specified in the Affordable Care Act. In addition, OAH will use the performance data to

inform planning and resource allocation decisions; identify training, technical assistance, and evaluation needs; and provide Congress, OMB, and the general public with information about the individuals who participate in PAF-funded activities and the range and scope of services they receive.

Likely Respondents: States and Tribes that are PAF grant awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The table below summarizes the total annual burden hours estimated for this ICR.

EXHIBIT 3—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per respondent	Total burden hours
Participant & Partner Characteristics (17 measures).	All Grantees	17	1	19	323
Category 1 Measures (4 measures).	Category 1 Grantees: Implementing activities to support pregnant and parenting student services at institutions of higher education.	2	1	6	12
Category 2 Measures (6 measures).	Category 2 Grantees: Implementing activities to support pregnant and parenting teens at high schools and community service centers.	14	1	9	126
Category 3 Measures (2 measures).	Category 3 Grantees: Implementing activities to improve services for pregnant women who are victims of domestic violence, sexual violence, sexual assault, and stalking.	6	1	3	18
Category 4 Measures (1 measure).	Category 4 Grantees: Implementing public awareness and education activities.	13	1	1	13
Total	17	492

The Offices of the Secretary specifically requests comments on (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Keith A. Tucker,
Information Collection Clearance Officer.
 [FR Doc. 2013–23176 Filed 9–23–13; 8:45 am]
BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Service (HHS), Office of the Secretary, Office of Minority Health (OMH) announces the publication of the final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care*, known as the enhanced National CLAS Standards. In developing the enhanced National CLAS Standards, OMH undertook the National CLAS Standards Enhancement Initiative. From 2010–2012, this initiative included input from a National Project Advisory Committee composed of subject matter experts representing public, private and government sectors, regional public meetings, public comment period, and a systematic literature review. The enhanced National CLAS Standards, including a brief background summary of the development process and public comment period, are printed below.

DATES: The final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care* will be available beginning September 24, 2013.

ADDRESSES: The final enhanced *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care* can be found online at www.thinkculturalhealth.hhs.gov.

FOR FURTHER INFORMATION CONTACT: CDR Jacqueline Rodrigue, Deputy Director, Office of Minority Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852. Attn: Enhanced National CLAS Standards. Telephone: (240) 453–2882.

SUPPLEMENTARY INFORMATION: In 2001, the HHS OMH published the *National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care*, known as the original National CLAS Standards, to address inequities that existed in the provision of health services, and to make these services more responsive to the individual needs of all patients and consumers. The original National CLAS Standards resulted from extensive research, discussions, input from stakeholders across the country, and offered a practical framework for the implementation of services and organizational structures that helped health care organizations and providers become more responsive to culturally and linguistically diverse communities. For the past decade, the original National CLAS Standards have served as catalyst and conduit for efforts to

improve the quality of care and achieve health equity.

The HHS OMH undertook the National CLAS Standards Enhancement Initiative from 2010 to 2012 to recognize the nation's increasing diversity, to reflect the tremendous growth in the fields of cultural and linguistic competency over the past decade, and to ensure relevance with new national policies and legislation, such as the Affordable Care Act. A decade after the publication of the original National CLAS Standards, there is still much work to be done. Racial and ethnic disparities in health and health care remain a significant public health issue, despite advances in health care technology and delivery, even when factors such as insurance coverage, income, and educational attainment are taken into account. Cultural and linguistic competency strives to improve the quality of care received and to reduce disparities experienced by racial and ethnic minorities and other underserved populations. Through the National CLAS Standards Enhancement Initiative (Enhancement Initiative), a new benchmark is being established for culturally and linguistically appropriate services to improve the health of all individuals.

The Enhancement Initiative followed the same development process as the original National CLAS Standards project in 1999–2001. The development process had three major components: (1) Input from a National Project Advisory Committee comprised of subject matter experts representing public, private, and government sectors; (2) regional public meetings, public comment period; and (3) a systematic literature review. The goals of the Enhancement Initiative were to update the original National CLAS Standards in order to reflect the advancements of the past decade, expand their scope, and improve upon their clarity in order to encourage more widespread understanding and implementation. The Enhancement Initiative also sought to develop a product that could assist individuals and organizations in the implementation of the enhanced National CLAS Standards.

Public Comment Period and Regional Public Meetings

As part of the National CLAS Standards Enhancement Initiative, OMH invited the public to submit comments on the original National CLAS Standards in late 2010, with the purpose of increasing public awareness of the National CLAS Standards. The announcement of the public comment period appeared in the **Federal Register**

published on September 23, 2010 (75 FR 57957–58), at www.thinkculturalhealth.hhs.gov/CLCCHC/HealthNews/FederalRegister_CLAS.pdf.

The **Federal Register** announcement highlighted the various ways in which the public could provide comment, including submitting comments via an online portal, or submitting letters directly to OMH and/or its support team at SRA International, Inc. Individuals and organizations were encouraged to review the original National CLAS Standards and send written and/or online public comments during a 103-day period between September 20, 2010, and December 31, 2010. Over 500 individuals and 90 organizations participated in the public comment period.

Concurrent with the public comment period, three in-person regional public meetings were convened. The purpose of the regional public meetings was to gather and solicit detailed feedback from interested individuals and organizations that would complement and enhance the public comments received by OMH through online and written submissions. These three public meetings were held on October 22, 2010, in Baltimore, Maryland; November 4, 2010, in San Francisco, California; and on November 15, 2010, in Chicago, Illinois. The total number of attendees for all three meetings was approximately 100 individuals from different organizations. The project team recorded and transcribed all three meetings. A qualitative theme analysis of the public meetings' transcripts was completed to determine relevant themes.

Analysis and Response to Public Comments Meetings on the enhanced National CLAS Standards

The following themes arose from the comments heard across the three public meetings.

The enhanced National CLAS Standards should:

- Encompass a broad definition of culture to include religion and spirituality; lesbian, gay, bisexual, and transgender community individuals; deaf and hearing impaired individuals; and blind and vision impaired individuals
- Incorporate the areas of patient satisfaction and safety
- Address issues of health literacy
- Establish congruency with other standards in the field
- Be action oriented
- Reflect advancements in terminology, technology, and more,

including medical homes, electronic health records, and language access.

Analysis and Response to Written and Online Comments on the enhanced National CLAS Standards

A series of Likert-type statements were posed to those responding via the online portal and written submissions, and respondents were asked to indicate the degree to which they agreed or disagreed with each statement. Examples of the statements and responses are as follows:

1. "The National CLAS Standards meet my needs."

Fifty-nine percent (59%) of the respondents either strongly agreed or agreed with the statement that the original National CLAS Standards met their needs as someone who works to improve the health of diverse communities. In a follow-up question, "In order for the CLAS Standards to meet my needs, the following enhancements would need to be made:" 29%, (n=51) of the respondents requested additional resources (e.g., additional training, funding, guides). In addition, 13% (n=24) requested CLAS enforcement mechanisms, 7% (n=13) requested promotion (i.e., need for increased awareness), 7% (n=13) requested increased clarity, and 7% (n=12) requested increased inclusivity of the populations addressed.

2. "I believe the National CLAS Standards [as a whole] should be revised" Forty-eight percent (48%) of respondents either strongly agreed or agreed with the statement that the CLAS Standards should be revised. In a follow-up question, "I believe with revisions my utilization of the CLAS Standards will * * *" 29% (n=103) indicated that their utilization of the CLAS Standards would increase upon revision, while 25% (n=88) indicated that their utilization would stay the same. Similarly, 32% (n=113) of respondents indicated their belief that their organization's utilization of the CLAS Standards would increase upon revision.

After December 31, 2010, when the public comment period ended, the project team analyzed the public comments received from all sources, including the 90 organizations that submitted online or written public comments. The following overarching themes emerged:

The enhanced National CLAS Standards should:

- Expand the target audience beyond health care organizations
- Encompass a broad definition of culture to include religion and spirituality; lesbian, gay, bisexual, and

transgender individuals; deaf and hearing impaired individuals; and blind and vision impaired individuals

- Offer more guidance pertaining to language assistance services
- Establish congruency with other related standards in the field.

National Project Advisory Committee

The National Project Advisory Committee (NPAC) of National CLAS Standards Enhancement Initiative is comprised of 36 subject matter experts in the fields of cultural and linguistic competency representing HHS agencies, academic institutions, health associations, and other private organizations. A complete list of NPAC members is available at www.thinkculturalhealth.hhs.gov. The NPAC provided insight, recommendations, and review throughout the development of the enhanced National CLAS Standards. The Enhancement Initiative Project Team conducted informal interviews in fall 2010 with the members of the NPAC to gather input on the enhanced National CLAS Standards from subject matter experts representing a myriad of roles in the field of cultural and linguistic competency. These conversations, along with the public comment and the systematic literature review, served to begin the laying of the foundation for the enhanced National CLAS Standards in fall 2010. The topics of discussion included the purpose and scope of the future National CLAS Standards, the target audience, and issues surrounding implementation and promotion.

The NPAC convened twice in Washington, DC during 2011. At the January 2011 meeting, the NPAC discussed the following topics in depth: Purpose, Definitions, Inclusivity, Audience, Health Literacy, Language Access Services, Measurements, Implementation, Promotion, and End Product.

The January 2011 meeting built the framework for the Project Team to begin drafting the enhanced National CLAS Standards. During spring 2011, the NPAC reviewed and provided feedback on a document of terminology and definitions that would serve as the conceptual underpinning of the enhanced National CLAS Standards. The NPAC met virtually for a series of webinars in summer 2011 to define the direction of the enhanced National CLAS Standards and discuss draft Standards. Another recurring theme throughout the public comment portion of the National CLAS Standards Enhancement Initiative was the request for additional support and guidance in

the implementation and maintenance of the National CLAS Standards. To address this issue, the NPAC began compiling information and materials for the guidance document, *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care: A Blueprint for Advancing and Sustaining CLAS Policy and Practice (The Blueprint)* to accompany the enhanced National CLAS Standards. *The Blueprint*, which describes each stage of the development process, is available at www.thinkculturalhealth.hhs.gov.

Systematic Literature Review

The systematic literature review, developed in 2010, discusses the evolution of the efforts to improve cultural and linguistic appropriateness since the publication of the original National CLAS Standards in 2001. It addresses the broad dissemination, promotion, and implementation nationwide of the National CLAS Standards and the concepts of CLAS. In addition, the report covers cultural competency education initiatives; adoption of CLAS at the federal, state, and organizational levels; changes in accreditation standards to explicitly include CLAS; the proliferation of technical assistance regarding CLAS; and research and evaluation of the National CLAS Standards' impact. The report concludes with areas for consideration that emerged from the literature and research of the last 10 years, which provided insight into the issues the enhanced National CLAS Standards should address.

Rationale for the Enhancement of the CLAS Standards

The public comments from the online portal, the written submissions, the regional public meetings, systematic literature review, and the NPAC offered a great pool of suggestions on how to enhance the National CLAS Standards. The enhanced *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* are composed of 15 Standards that provide individuals and organizations with a blueprint for successfully implementing and maintaining culturally and linguistically appropriate services. Culturally and linguistically appropriate health care and services, broadly defined as care and services that are respectful of and responsive to the cultural and linguistic needs of all individuals, are increasingly seen as essential to reducing disparities and improving health care quality.

All 15 Standards are necessary to advance health equity, improve quality,

and help eliminate health care disparities. As important as each individual Standard is, the exclusion of any Standard diminishes health professionals' and organizations' ability to meet an individual's health and health care needs in a culturally and linguistically appropriate manner. Thus, it is strongly recommended that each of the 15 Standards be implemented by health and health care organizations.

Statement of Intent

In response to public comment and the National Project Advisory Committee feedback requesting further clarification on the intent of the National CLAS Standards, a statement of intent for the enhanced National CLAS Standards was crafted and has been added as an introductory sentence to the Standards:

The National CLAS Standards are intended to advance health equity, improve quality, and help eliminate health care disparities by establishing a blueprint for health and health care organizations to:

As the enhanced National CLAS Standards are disseminated, the inclusion of the statement of intent within the actual Standards ensures that every person who uses the Standards will understand their importance. Although this introductory sentence does not convey the only purpose of the Standards, it does convey their primary goal. The addition of the statement of intent ties the culturally and linguistically competent policies and practices posed in the enhanced National CLAS Standards directly to the goals of advancing health equity, improving quality, and eliminating health care disparities.

Advance Health Equity

Health equity is defined as the attainment of the highest level of health for all people (HHS OMH, National Stakeholder Strategy for Achieving Health Equity, 2011). Currently, many individuals are unable to attain their highest level of health for several reasons, including social factors such as inequitable access to quality care and individual factors such as limited resources. Lack of health equity has a significant economic and societal impact.

Improve Quality

Culturally and linguistically appropriate services and related education initiatives affect several aspects of an organization's continuous quality improvement initiatives. For example, research suggests that after implementation of CLAS initiatives,

there are substantial increases in provider knowledge and skill acquisition and improvements in provider attitudes toward culturally and linguistically diverse patient populations.¹ Studies also indicate that patient satisfaction increases when culturally and linguistically appropriate services are delivered.² At the organizational level, hospitals and clinics that support effective communication by addressing CLAS have been shown to have higher patient-reported quality of care and more trust in the organization.³ Preliminary research has shown a positive impact of CLAS on patient outcomes,⁴ and a growing body of evidence illustrates the effectiveness of culturally and linguistically appropriate services in improving the quality of care and services received by individuals.⁵

Help Eliminate Health Care Disparities

Eliminating health care disparities is one of the ultimate goals of advancing health equity. Disparities exist and persist across many culturally diverse groups, with individuals who identify as racial or ethnic minorities being less

likely to receive preventive health services, even when insured.⁶

Clarity and Action

Each of the National CLAS Standards was revised for greater clarity and focus. In addition, the wording of each of the 15 Standards now begins with an action word to emphasize how the desired goal may be achieved.

Standards of Equal Importance

The original National CLAS Standards designated each Standard as a recommendation, mandate, or guideline. The recommendation (original 14 Standards) was a suggestion for voluntary adoption by health care organizations. The mandates (original Standards 4, 5, 6, and 7) were Federal requirements for all recipients of Federal funds. The guidelines (original Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13) were activities recommended for adoption as mandates by federal, state, and national accrediting agencies.

However, the enhanced National CLAS Standards promote collective adoption of all Standards as the most effective approach to improve the health and well-being of all individuals. The Standards are intended to be used together, as mutually reinforcing actions, and each of the 15 Standards should be understood as an equally important guideline to advance health equity, improve quality, and help eliminate health care disparities.

Although the enhanced National CLAS Standards are not statutory or regulatory requirements, failure by a recipient of Federal financial assistance to provide services consistent with Standards 5 through 8 (Communication and Language Assistance Standards) could result in a violation of Title VI of the Civil Rights Act of 1964 and its implementing regulations (42 USC 2000d et seq. and 45 CFR Part 80). Therefore, implementation of these goals may help ensure that health care organizations and individual providers serve persons of diverse backgrounds in a culturally and linguistically appropriate manner in accordance with the law. Health care organizations and individual providers are encouraged to seek technical assistance from the HHS Office for Civil Rights or review the *HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited*

¹ Beach, M.C., Cooper, L.A., Robinson, K.A., Price, E.G., Gary, T.L., Jenckes, M.W., ... Powe, N.R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality Web site: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>.

² Beach, M.C., Cooper, L.A., Robinson, K.A., Price, E.G., Gary, T.L., Jenckes, M.W., * * * Powe, N.R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality Web site: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>.

³ Wynia, M.K., Johnson, M., McCoy, T.P., Passmore Griffin, L., & Osborn, C.Y. (2010). Validation of an organizational communication climate assessment toolkit. *American Journal of Medical Quality*, 25(6), 436-443. doi:10.1177/1062860610368428.

⁴ Lie, D.A., Lee-Rey, E., Gomez, A., Berecknyel, S., & Braddock, C.H. (2010). Does cultural competency training of health professionals improve patient outcomes? A systematic review and proposed algorithm for future research. *Journal of General Internal Medicine*, 26(3), 317-325. doi:10.1007/s11606-010-1529-0.

⁵ Beach, M.C., Cooper, L.A., Robinson, K.A., Price, E.G., Gary, T.L., Jenckes, M.W., ... Powe, N.R. (2004). Strategies for improving minority healthcare quality. (AHRQ Publication No. 04-E008-02). Retrieved from the Agency of Healthcare Research and Quality Web site: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf>.

Goode, T.D., Dunne, M.C., & Bronheim, S. M. (2006). The evidence base for cultural and linguistic competency in health care. (Commonwealth Fund Publication No. 962). Retrieved from The Commonwealth Fund Web site: http://www.commonwealthfund.org/usr_doc/Goode_evidencebasecultlinguisticcomp_962.pdf.

⁶ DeLaet, D.E., Shea, S., & Carrasquillo, O. (2002). Receipt of preventive services among privately insured minorities in managed care versus fee-for-service insurance plans. *Journal of General Internal Medicine*, 17, 451-457. doi:10.1046/1525-1497.2002.10512.x.

English Proficient Persons document (HHS Office for Civil Rights, 2003) to assess whether or to what extent language access services must be provided in order to comply with the Title VI requirement to take reasonable steps to provide meaningful access to their programs for persons with limited English proficiency.

Principal Standard and Three Enhanced Themes

Principal Standard

Standard 1 has been made the Principal Standard with the understanding that it frames the essential goal of all of the Standards, and if the other 14 Standards are adopted, implemented, and maintained, then the Principal Standard will be achieved.

1. Provide effective, equitable, understandable, respectful, and quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

Theme 1: Governance, Leadership, and Workforce

Changing the name of Theme 1 from *Culturally Competent Care to Governance, Leadership, and Workforce* provides greater clarity on the specific locus of action for each of these Standards and emphasizes the importance of the implementation of CLAS as a systemic responsibility, requiring the investment, support, and training of all individuals within an organization.

The Standards in this theme include:

2. Advance and sustain governance and leadership that promotes CLAS and health equity
3. Recruit, promote, and support a diverse governance, leadership, and workforce
4. Educate and train governance, leadership, and workforce in CLAS

Theme 2: Communication and Language Assistance

Changing the name of Theme 2 from *Language Access Services to Communication and Language Assistance* broadens the understanding and application of appropriate services to include all communication needs and services, including sign language, braille, oral interpretation, and written translation.

The Standards in this theme include:

5. Offer communication and language assistance
6. Inform individuals of the availability of language assistance

7. Ensure the competence of individuals providing language assistance

8. Provide easy-to-understand materials and signage

Theme 3: Engagement, Continuous Improvement, and Accountability

Changing the name of Theme 3 from *Organizational Supports to Engagement, Continuous Improvement, and Accountability* underscores the importance of establishing individual responsibility in ensuring that CLAS is supported, while retaining the understanding that effective delivery of CLAS demands actions across an organization. This revision focuses on the supports necessary for adoption, implementation, and maintenance of culturally and linguistically appropriate policies and services regardless of one's role within an organization or practice. All individuals are accountable for upholding the values and intent of the National CLAS Standards.

The Standards in this theme include:

9. Infuse CLAS goals, policies, and management accountability throughout the organization's planning and operations
10. Conduct organizational assessments
11. Collect and maintain demographic data
12. Conduct assessments of community health assets and needs
13. Partner with the community
14. Create conflict and grievance resolution processes
15. Communicate the organization's progress in implementing and sustaining CLAS.

The past decade has shown that the National CLAS Standards are a dynamic framework. Therefore, as best and promising practices in the field of cultural and linguistic competence develop, there will be future enhancements of the National CLAS Standards. The HHS OMH also maintains a Web version of *The Blueprint* to provide a more comprehensive and up-to-date resource, with supporting material online at www.thinkculturalhealth.hhs.gov.

Dated: September 11, 2013.

J. Nadine Gracia,

Deputy Assistant Secretary for Minority Health, Office of Minority Health, U.S. Department of Health and Human Services.

[FR Doc. 2013-23164 Filed 9-23-13; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Board Public Meeting Times and Dates (All times are Mountain Time):
8:15 a.m.–5:00 p.m., October 16, 2013.
8:15 a.m.–12:00 p.m., October 17, 2013.

Public Comment Times and Dates (All times are Mountain Time):
5:00 p.m.–6:00 p.m.*, October 16, 2013.

*Please note that the public comment periods may end before the times indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.

Place: Doubletree by Hilton Denver—Westminster, 8773 Yates Drive, Westminster, CO 80031, Phone: (303) 427-4000; Fax: (303) 426-1680. Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1-866-659-0537 with a pass code of 9933701. Live Meeting CONNECTION: <https://www.livemeeting.com/cc/cdc/join?id=7B82CG&role=attend&pw=ABRWH>; Meeting ID: 7B82CG; Entry Code: ABRWH

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being

4. Disparity Impact Statement (DIS)

Disparity impact statements are a part of a comprehensive data-driven approach for identifying and addressing health disparities to promote health equity for racial and ethnic minority populations. A DIS refers to the demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities.

The DIS will provide the measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and overarching goal of advancing health equity.

Agencies within the U.S. Department of Health and Human Services offer resources to support developing a Disparity Impact Statement, including the following:

- Building an Organizational Response to Health Disparities: Disparities Impact Statement (<https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf>)
- HDPulse — An Ecosystem of Minority Health and Health Disparities Resources (<https://www.nimhd.nih.gov/resources/hd-pulse.html>)

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