

**Department of Health and Human Services
Substance Abuse and Mental Health Services
Administration**

**FY 2023 National Center of Excellence for Tobacco-
Free Recovery**

(Short Title: National Center-TFR)

(Initial Announcement)

Notice of Funding Opportunity (NOFO) No. SM-23-019

Assistance Listing Number: 93.243

Key Dates:

Application Deadline	Applications are due by May 16, 2023.
Intergovernmental Review (E.O. 12372)	Applicants must comply with E.O. 12372 if their state(s) participates. Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after the application deadline.
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination	Applicants must send the PHSIS to appropriate state and local health agencies by the application deadline. Comments from the Single State Agency are due no later than 60 days after the application deadline.

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP), is accepting applications for the fiscal year (FY) 2023 National Center of Excellence for Tobacco-Free Recovery program (Short title: National Center-TFR). The purpose of this program is to establish and/or maintain a national center of excellence with specialized subject matter expertise in commercial¹ tobacco use cessation among persons with mental and/or substance use disorders. The award recipient will be expected to create results-oriented collaborations among stakeholder organizations and educate/train behavioral health providers. With this program, SAMHSA aims to reduce the high rate of tobacco use among individuals with mental and/or substance use disorders.

Funding Opportunity Title:	Center of Excellence for Tobacco-Free Recovery (Short Title: National Center-TFR)
Funding Opportunity Number:	SM-23-019
Due Date for Applications:	May 16, 2023
Estimated Total Available Funding:	\$1,250,000
Estimated Number of Awards:	One award
Estimated Award Amount:	Up to \$1,250,000 per year per award
Cost Sharing/Match Required:	No
Length of Project Period:	Up to five years

¹ When SAMHSA references tobacco, it is in reference to the use of commercial tobacco and not the sacred and traditional use of tobacco by some American Indian communities.

Anticipated Project Start Date:	September 30, 2023
Anticipated Award Date:	August 31, 2023
Eligible Applicants:	Eligible applicants are domestic public and private non-profit entities. [See Section III-1 for complete eligibility information.]
Authorizing Statute:	Sec. 1920 and Sec. 1935 of the Public Health Services Act.

Be sure to check the SAMHSA website periodically for any updates on this program.

All applicants MUST be registered with NIH's [eRA Commons](#), [Grants.gov](#), and the System for Award Management ([SAM.gov](#)) in order to submit this application. The process could take up to six weeks. (See [Appendix A](#) of this NOFO for all registration requirements).

If you are not currently registered with the eRA Commons, Grants.gov, and/or SAM.gov, you MUST begin the registration process immediately. If you are already registered in these systems, please confirm your SAM registration is still active and you are able to access your Grants.gov and eRA Commons accounts.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- **The applicant organization MUST be registered in NIH's eRA Commons;**
- AND**
- **The Project Director MUST have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.**

No exceptions will be made.

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

I. PROGRAM DESCRIPTION

1. PURPOSE

The purpose of the National Center of Excellence for Tobacco-Free Recovery program is to establish and/or maintain a national center of excellence with specialized subject matter expertise in commercial tobacco use cessation among persons with mental and/or substance use disorders. This program provides technical assistance to states, local governments, tribal communities, behavioral health organizations, primary care providers, clinicians, peers, families, and other stakeholders. The award recipient will be expected to create results-oriented collaborations among stakeholder organizations and educate/train behavioral health providers in commercial tobacco use cessation. The goal of the program is to reduce the high rate of tobacco use among individuals with mental and/or substance use disorders.

As overall smoking rates have declined, the prevalence of smoking among people with behavioral health disorders has remained high^{2,3}. Although people with behavioral health conditions represent about 25 percent of the U.S. adult population, they account for nearly 40 percent of all cigarettes smoked⁴. A study using large public health datasets found that nearly half of all deaths were tobacco-related for persons who received substance abuse services, or who received both substance abuse and mental health services. In addition, the study showed that those who received mental health services alone were more likely to die earlier from tobacco-related deaths than the general population.⁵ This disparity is causing serious health consequences.

Many behavioral health facilities do not provide tobacco cessation counseling. The 2021 National Substance Use and Mental Health Services Survey shows that only 64.9 percent of substance use treatment facilities and 51.7 percent of mental health treatment facilities provide tobacco cessation counseling.⁶ A growing body of research shows that quitting smoking can improve health and wellness as well as mental health and addiction recovery outcomes. Studies show that quitting smoking can decrease

² Han B, Volkow ND, Blanco C, Tipperman D, Einstein EB, Compton WM. Trends in Prevalence of Cigarette Smoking Among US Adults With Major Depression or Substance Use Disorders, 2006-2019. JAMA. 2022 Apr 26;327(16):1566-1576. doi: 10.1001/jama.2022.4790. PMID: 35471512; PMCID: PMC9044114.

³ National Institute on Drug Abuse. 2022, May 25. Do people with mental illness and substance use disorders use tobacco more often? Retrieved from <https://nida.nih.gov/publications/research-reports/tobacco-nicotine-e-cigarettes/do-people-mental-illness-substance-use-disorders-use-tobacco-more-often> on 2023, February 6.

⁴ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The NSDUH Report. March 20, 2013. <http://www.samhsa.gov/data/sites/default/files/spot104-cigarettes-mental-illness-substance-use-disorder/spot104-cigarettes-mental-illness-substance-use-disorder.pdf>

⁵ Bandiera FC, Anteneh B, Le T, Delucchi K, Guydish J. Tobacco-related mortality among persons with mental health and substance abuse problems. PLoS One. 2015 Mar 25;10(3):e0120581. doi: 10.1371/journal.pone.0120581. PMID: 25807109; PMCID: PMC4373726.

⁶ Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N-SUMHSS), 2021.

depression, anxiety, and stress⁷. For persons in addiction recovery, smoking cessation can increase long-term abstinence from alcohol and other drugs^{8,9}.

This National Center of Excellence for Tobacco-Free Recovery is authorized under the Sec. 1920 and Sec. 1935 of the Public Health Services Act.

2. KEY PERSONNEL

Key personnel are staff members who must be part of the project regardless of whether or not they receive a salary or compensation from the project. These staff members must make a substantial contribution to the execution of the project and should reflect SAMHSA's expectation of diversity, equity, and inclusion in the selection of staff.

Key Personnel for this program is the Project Director. The Project Director is responsible for oversight of the entire project. The Project Director must have:

- Extensive experience providing specialized technical assistance to address tobacco use by persons with behavioral health disorders;
- Extensive experience convening structured meetings to mobilize stakeholders to address tobacco use by persons with behavioral health disorders; and
- Specialized subject matter expertise on the myths and barriers related to tobacco cessation as well as evidence-based approaches to addressing tobacco use among persons with behavioral health disorders.

If awarded, the recipient will be notified by SAMHSA about whether the individual designated for this position has been approved. If recipient needs to replace a Key Personnel during the project period, the individual proposed for the vacant position requires prior approval by SAMHSA after a review of the credentials of the staff member and the job description.

⁷ Taylor G, McNeill A, Girling A, Farley A, Lindson-Hawley N, Aveyard P. Change in mental health after smoking cessation: systematic review and meta-analysis. *BMJ*. 2014 Feb 13;348:g1151. doi: 10.1136/bmj.g1151. Erratum in: *BMJ*. 2014;348:g2216. PMID: 24524926; PMCID: PMC3923980.

⁸ Tsoh JY, Chi FW, Mertens JR, Weisner CM. Stopping smoking during first year of substance use treatment predicted 9-year alcohol and drug treatment outcomes. *Drug Alcohol Depend*. 2011 Apr 1;114(2-3):110-8. doi: 10.1016/j.drugalcdep.2010.09.008. Epub 2010 Nov 2. PMID: 21050681; PMCID: PMC3062692.

⁹ Weinberger AH, Platt J, Esan H, Galea S, Erlich D, Goodwin RD. Cigarette Smoking Is Associated With Increased Risk of Substance Use Disorder Relapse: A Nationally Representative, Prospective Longitudinal Investigation. *J Clin Psychiatry*. 2017 Feb;78(2):e152-e160. doi: 10.4088/JCP.15m10062. PMID: 28234432; PMCID: PMC5800400.

3. REQUIRED ACTIVITIES

Required activities are the activities that award recipient must implement. They must be reflected in the Project Narrative of your application. This is in response to [Section V](#) of this NOFO.

These are the activities that the recipient is expected to implement.

- Convene two leadership academies for tobacco-free recovery per year to bring together stakeholders, including consumers and family members, at the state and/or national levels to develop and implement an action plan related to tobacco-free recovery in behavioral health care settings. The academies may be in-person or virtual as decided by a planning committee of key stakeholders. The leadership academies must use an organized, results-oriented process or model that will:
 - Build cohesion among stakeholders to collaborate and work together;
 - Build agreement on baselines and target measure(s) to monitor progress;
 - Develop an action plan with a clear process for implementation and roles of all stakeholders; and
 - Keep stakeholders engaged and actively involved beyond the leadership academy.
- Provide tailored and customized technical assistance to states, behavioral health organizations, primary care providers, clinicians, peers, families, and other stakeholders regarding efforts to reduce tobacco use among individuals with mental and/or substance use disorders.
- Conduct webinars to educate and train behavioral health administrators, primary care providers, clinicians, peers, and other stakeholders on tobacco-free recovery in behavioral health care settings and effective evidence-based tobacco cessation interventions.
- Disseminate information on current research, evidence-based practices/policies, resources, training opportunities, and other relevant information related to tobacco cessation among persons with behavioral health disorders. Dissemination mechanisms include, but are not limited to, website, listservs, social media, and professional conference presentations.
- Develop and maintain a user-friendly website with resources and information on the above activities, including how to access technical assistance.

4. ALLOWABLE ACTIVITIES

Allowable activities are an allowable use of award funds but are not required. Allowable activities may include:

- Develop strategies, materials, and specialized training opportunities that enhance efforts to reduce tobacco use among persons with behavioral health disorders.
- Address in training activities any groups within the behavioral health population which have not shown significant progress in reducing tobacco use. For example, a recent study showed that American Indian or Alaska Native adults with major depressive episode did not show progress in reducing cigarette smoking from 2006 to 2019.¹⁰

5. DATA COLLECTION/PERFORMANCE MEASUREMENT AND PROJECT PERFORMANCE ASSESSMENT

All SAMHSA recipients are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010. Applicants must document a plan for data collection and reporting in the Project Narrative in response to [Section D: Data Collection and Performance Measurement](#) in Section V of this NOFO.

The recipient is required to report performance on the following measures:

- The number of people in the mental health and related workforce trained in tobacco cessation related practices/activities that are consistent with the goals of the grant.
- The number of organizations collaborating/coordinating/sharing resources with other organizations as a result of the grant.

This information will be gathered using a uniform data collection tool provided by SAMHSA. Recipient is required to submit data via SAMHSA's Performance Accountability and Reporting System (SPARS) and access will be provided upon award. Additional information about SPARS can be found here: <https://spars.samhsa.gov/content/data-collection-tool-resources>. Required data for the above measures are to be collected and reported quarterly into SPARS and reported

¹⁰ Han B, Volkow ND, Blanco C, Tipperman D, Einstein EB, Compton WM. Trends in Prevalence of Cigarette Smoking Among US Adults With Major Depression or Substance Use Disorders, 2006-2019. JAMA. 2022 Apr 26;327(16):1566-1576. doi: 10.1001/jama.2022.4790. PMID: 35471512; PMCID: PMC9044114.

annually in the written project performance assessment report referenced in the section below.

The collection of these data enables SAMHSA to report on key outcome measures relating to the program. In addition to these outcomes, performance measures collected by recipient will be used to demonstrate how SAMHSA's programs are reducing disparities in behavioral health access, service use, and outcomes nationwide.

Performance data will be reported to the public as part of SAMHSA's Congressional Budget Justification.

Project Performance Assessment

In addition, recipient is required to report annually on their progress addressing the goals and objectives identified in your Project Narrative. Recipient must periodically review the performance data they report to SAMHSA (as required above), assess their progress, and use this information to improve the management of their project. The annual report should include the following:

- Summary of state leadership academies including baseline tobacco use data of behavioral health populations and target goals/measures.
- Summary of webinars provided including number of webinars and number of participants.
- Resources developed.

The project performance assessment should be designed to help you determine whether you are achieving the goals, objectives, and outcomes you intend to achieve and whether adjustments need to be made to your project.

Performance assessments should be used to determine whether your project is having/will have the intended impact on behavioral health disparities. Recipient should also review the behavioral health Disparity Impact Statement they submitted in the first two months of the award. See [Section VI.3](#) for information on required progress reports.

See [Appendix E](#) and [Appendix F](#) for more information on responding this section.

6. OTHER EXPECTATIONS

SAMHSA Values That Promote Positive Behavioral Health SAMHSA expects recipients to use funds to implement high quality programs, practices, and policies that are

recovery-oriented, trauma-informed, and equity-based as a means of improving behavioral health.¹¹

Recovery is a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Recovery-oriented recipients promote partnerships with people in recovery from mental and substance use disorders and their family members to guide the behavioral health system and promote individual, program, and system-level approaches that foster: *Health*—managing one’s illnesses or symptoms and making informed healthy choices that support physical and emotional wellbeing; *Home*—a stable and safe place to live; *Purpose*—meaningful daily activities such as a job or school; and *Community*—supportive relationships with families, friends and peers. Recovery-oriented systems of care embrace recovery as: emerging from hope; person-driven; occurring via many pathways; holistic; supported by peers and allies; culturally-based and influenced; supported through relationship and social networks; involving individual, family, and community strengths and responsibility; supported by addressing trauma; and based on respect.

Trauma-informed Approaches recognize and intentionally respond to the lasting adverse effects of experiencing traumatic events. A trauma-informed approach is defined through six key principles:

- *Safety*: participants and staff feel physically and psychologically safe;
- *Peer support*: peer support and mutual self-help are key as vehicles for establishing safety and hope, building trust, enhancing collaboration, and utilizing their lived experience to promote recovery and healing;
- *Trustworthiness and Transparency*: Organizational decisions are conducted to build and maintain trust with participants and staff;
- *Collaboration and Mutuality*: importance is placed on partnering and leveling power differences between staff and service participants;
- *Cultural, Historical, & Gender Issues*: culture and gender-responsive services are offered while moving beyond stereotypes/biases;
- *Empowerment, Voice, and Choice*: organizations foster a belief in the primacy of the people who are served to heal and promote recovery from trauma.¹²

It is critical recipients promote the linkage to recovery and resilience for those individuals and families impacted by trauma.

¹¹ “**Behavioral health**” means the promotion of mental health, resilience and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

¹² https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf

Behavioral health equity is the right to access high-quality and affordable health care services and supports for all populations regardless of the individual's race, age, ethnicity, gender (including gender identity), disability, socioeconomic status, sexual orientation, or geographical location. By improving access to behavioral health care, promoting quality behavioral health programs and practice, and reducing persistent disparities in mental health and substance use services for underserved populations and communities, recipients can ensure that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with promoting access to high quality services, behavioral health disparities can be further mitigated by addressing social determinants of health, such as social exclusion, unemployment, adverse childhood experiences, and food and housing insecurity.

Behavioral Health Disparities

If your application is funded, you will be expected to develop a behavioral health Disparity Impact Statement (DIS) no later than 60 days after your award. ([See Appendix H –Addressing Behavioral Health Disparities](#)). Progress and evaluation of activities for tracking DIS efforts are also part of the annual progress reports (see [Section VI.3, Reporting Requirements](#)).

The DIS is a data-driven, quality improvement approach to advance equity for all, and to identify racial, ethnic, sexual and gender minority, and rural populations at highest risk for experiencing behavioral health disparities as part of their projects. The purpose of the DIS is for recipients to identify and address health disparities and to develop and implement an action plan with a disparity reduction and quality improvement process to close the identified gap(s). The aim is to achieve targeted behavioral health equity for disparate populations and improve systems.

The behavioral health disparity impact statement is in alignment with the expectations related to Executive Order 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

Tobacco and Nicotine-Free Policy

SAMHSA strongly encourages all recipients to adopt a tobacco/nicotine inhalation (vaping) product-free facility/grounds policy and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

Behavioral Health for Military Service Members and Veterans

SAMHSA encourages all recipients to address the behavioral health needs of active-duty military service members, returning veterans, and military families in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

Behavioral Health for Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Intersex (LGBTQI+) Individuals

In line with the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals (E.O. 14075) and the behavioral health disparities that the LGBTQI+ population face, SAMHSA encourages all recipients to address the behavioral health needs of the LGBTQI+ population in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

7. RECIPIENT MEETINGS

Recipient meetings will be held virtually and recipient is expected to fully participate in these meetings. If SAMHSA elects to hold an in-person meeting, budget revisions may be permitted.

II. FEDERAL AWARD INFORMATION

1. GENERAL INFORMATION

Funding Mechanism:	Grant Award
Estimated Total Available Funding:	\$1,250,000
Estimated Number of Awards:	One award
Estimated Award Amount:	Up to \$1,250,000 per year per award
Length of Project Period:	Up to five years
Anticipated State Date:	September 30, 2023

Proposed budgets cannot exceed \$1,250,000 in total costs (direct and indirect) in any year of the proposed project. Annual continuation awards will depend on the availability of funds, recipient progress in meeting project goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are domestic public and private nonprofit entities.

It is recommended that you review the information on eligibility in [Appendix C](#) of this NOFO.

2. COST SHARING and MATCHING REQUIREMENTS

Cost sharing/match is not required in this program.

3. OTHER REQUIREMENTS

- The Project Narrative must not exceed 10 pages. If the Project Narrative is over 10 pages, the application will not be considered for review.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

The application forms package specific to this funding opportunity can be accessed through [Grants.gov Workspace](#) or [eRA ASSIST](#). Due to difficulties with internet access, SAMHSA understands that applicants may have a need to request paper copies of materials, including forms and required documents. See [Appendix A](#) for more information on obtaining an application package.

2. CONTENT AND FORM OF APPLICATION SUBMISSION

REQUIRED APPLICATION COMPONENTS

The standard and supporting documents that must be submitted with the application are outlined below and in [Appendix A - 2.2](#) Required Application Components of this NOFO.

All files uploaded as part of the application must be in Adobe PDF file format. See [Appendix B](#) of this NOFO for formatting and validation requirements.

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver of this requirement in advance. See [Appendix A - 3.2](#) Waiver of Electronic Submission of this NOFO.

- **SF-424** – Fill out all Sections of the SF-424.
 - In **Line #4** (i.e., Applicant Identifier), input the Commons Username of the PD/PI.
 - In **Line #17** input the following information: (Proposed Project Date: a. Start Date: 9/30/2023; b. End Date: 9/29/2028).

New applicants should review the sample of a [completed SF-424](#)

- **SF-424A BUDGET INFORMATION FORM** – Fill out all Sections of the SF-424A using the instructions below. **The totals in Sections A, B, and D must match.**

- **Section A – Budget Summary:** If cost sharing/match is **not required**, use the first row only (Line 1) to report the total federal funds (e) and non-federal funds (f) requested for the **first year** of your project only. If cost sharing/match **is required**, use the **second row** (Line 2) to report the total non-federal funds (f) for the **first year** of your project only.
- **Section B – Budget Categories:** If cost sharing/match is **not required**, use the first column only (Column 1) to report the budget category breakouts (Lines 6a through 6h) and indirect charges (Line 6j) for the total funding requested for the **first year** of your project only. If cost sharing/match is required, you must use the second column (Column 2) to report the budget category breakouts for the **first year** of your project only.
- **Section C –**If cost sharing/match is **not required** leave this section blank. If cost sharing/match **is required** use the second row (line 9) to report non-federal match for the **first year** only.
- **Section D – Forecasted Cash Needs:** Input the total funds requested, broken down by quarter, only for **Year 1** of the project period. Use the first row for federal funds and the second row (Line 14) for **non-federal** funds.
- **Section E – Budget Estimates of Federal Funds Needed for the Balance of the Project:** Enter the total funds requested for the out years (e.g., Year 2, Year 3, Year 4, and Year 5). For example, if you are requesting funds for five years in total, enter the requested budget amount for each budget period in columns b, c, d, and e (i.e., 4 out years). - (b) First column is the budget for the second budget period; (c) Second column is the budget for the third budget period; (d) Third column is the budget for the fourth budget period; (e) Fourth column is the budget for the fifth budget period. Use Line 16 for federal funds and Line 17 for non-federal funds.

See [Appendix B](#) of this NOFO to review common errors in completing the SF-424 and the SF-424A. These errors will prevent your application from being successfully submitted.

The following pdf is a sample of a completed SF-424A form:

- [Sample SF-424A \(No Match Required\)](#)

See [Appendix L](#) for information on the SAMHSA Budget Template. **It is highly recommended that you use the template.**

- **PROJECT NARRATIVE – (Maximum 10 pages total)**

The Project Narrative describes your project. It consists of Sections A through D. (Remember that if your Project Narrative starts on page 5 and ends on page 15, it is 11 pages long, not 10 pages.) More detailed instructions for completing each section of the Project Narrative are provided in [Section V.1](#) – Application Review Information.

- **BUDGET JUSTIFICATION AND NARRATIVE**

The budget justification and narrative must be submitted as a file entitled “BNF” (Budget Narrative Form) when you submit your application into Grants.gov. (See [Appendix A](#) – 2.2 Required Application Components.)

- **ATTACHMENTS 1 THROUGH 8**

Use only the attachments listed below. If your application includes any attachments not required in this document, they will be disregarded.

Do not use attachments to extend or replace any of the sections of the Project Narrative. Reviewers will not consider them if you do.

Label the attachments as: Attachment 1, Attachment 2, etc. (Use the Other Attachments Form if applying with Grants.gov Workspace or Other Narrative Attachments if applying with eRA ASSIST.)

- ***Attachment 1: Letters of Commitment***

Include Letters of Commitment from any organization(s) partnering in the proposed project. **(Do not include any letters of support. Reviewers will not consider them if you do.)**

- ***Attachment 2: Data Collection Instruments/Interview Protocols***

If you are using standardized data collection instruments/interview protocols, you do not need to include these in your application. Instead, provide a web link to the appropriate instrument/protocol. If the data collection instrument(s) or interview protocol(s) is/are not standardized, you must include a copy in Attachment 2.

- ***Attachment 3: Sample Consent Forms***

Not Applicable to this NOFO

- ***Attachment 4: Project Timeline***

This attachment is scored by reviewers. Maximum of 2 pages. See instructions in [Section V, B.3](#) of this NOFO.

- **Attachment 5: Biographical Sketches and Position Descriptions**
See [Appendix G](#) of this NOFO for information on completing biographical sketches and job descriptions. Position descriptions should be no longer than one page each and biographical sketches should be two pages or less.
- **Attachment 6: Letter to the Single State Agency (SSA)**
See [Appendix J](#) of this NOFO for Intergovernmental Review (E.O. 12372) Requirements, if applicable.
- **Attachment 7: Confidentiality and SAMHSA Participant Protection/ Human Subjects Guidelines**
This attachment is in response to [Appendix D](#) of this NOFO and is a **required attachment**.
- **Attachment 8: Documentation of Non-profit Status**
All non-profit entities must submit documentation of their non-profit status. Any of the following is acceptable evidence of non-profit status:
 - A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code.
 - A copy of a currently valid Internal Revenue Service tax exemption certificate.
 - A statement from a State taxing body, State Attorney General, or other appropriate state official certifying the applicant organization has a non-profit status.
 - A certified copy of the organization's certificate of incorporation or similar document that establishes non-profit status; or
 - Any of the above proof for a state or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

3. UNIQUE ENTITY IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT

See [Appendix A](#) for information about the four registration processes that must be completed including obtaining a Unique Entity Identifier and registering with the System for Award Management (SAM). You must continue to maintain an active SAM registration with current information during the time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)).

4. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **May 16, 2023**. If an organization is submitting more than one application, the project title should be different for each application.

If you have been granted permission to submit a paper copy, the application must be received by the above date and time. See [Appendix A](#) of this NOFO for information on how to apply.

All applicants MUST be registered with NIH's [eRA Commons](#), [Grants.gov](#), and the System for Award Management ([SAM.gov](#)) in order to submit this application. The process could take up to six weeks. (See [Appendix A](#) of this NOFO for all registration requirements).

If you are not currently registered with the eRA Commons, Grants.gov, and/or SAM.gov, you MUST begin the registration process immediately. If you are already registered in these systems, please confirm your SAM registration is still active and you are able to access your Grants.gov and eRA Commons accounts.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- The applicant organization **MUST** be registered in NIH's eRA Commons;
AND
- The Project Director **MUST** have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.

No exceptions will be made.

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

5. FUNDING LIMITATIONS/RESTRICTIONS

The funding restrictions for this project are as follows:

- No more than 20 percent of the award for the budget period may be used for data collection, performance measurement, and performance assessment expenses.

- The indirect cost rate may not exceed **8 percent** of the proposed budget. Even if an organization has an established indirect cost rate, under training awards, SAMHSA reimburses indirect costs at a fixed rate of **8 percent** of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and sub-awards and contracts in excess of \$25,000. (45 CFR Part 75.414)

SAMHSA recipients must also comply with SAMHSA’s standard funding restrictions, which are included in [Appendix I](#) – Standard Funding Restrictions.

6. INTERGOVERNMENTAL REVIEW (E.O. 12372) REQUIREMENTS

All SAMHSA programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (HHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. See [Appendix J](#) for additional information on these requirements as well as requirements for the Public Health System Impact Statement (PHSIS).

7. OTHER SUBMISSION REQUIREMENTS

See [Appendix A](#) for specific information about submitting your application.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

The Project Narrative describes what you intend to do with your project and includes the Evaluation Criteria in Sections A-D below. Your application will be reviewed and scored according to your response to the requirements in Sections A-D.

In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.

- The Project Narrative (Sections A-D) together may be no longer than **10 pages**. You must use the four sections/headings listed below in developing your Project Narrative. **You must indicate the Section letter and number in your response, i.e., type “A-1”, “A-2”, etc., before your response to each question.** You do not need to type the full criterion in each section. You only need to include the letter and number of the criterion. You may not combine two or more questions or refer to another section of the Project Narrative in your response, such as indicating that the response for B.2 is in C.7. **Only information included in the appropriate numbered question will be considered by reviewers.** Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual bullets, each bullet is assessed in deriving the overall Section score.
- Any cost-sharing proposed in your application will not be a factor in the evaluation of your response to the Evaluation Criteria.

SECTION A: Statement of Need (20 points – approximately 2 pages)

1. Describe the extent of the problem, including service gaps and barriers related to reducing tobacco use by persons with behavioral health disorders. Identify the source of data.
2. Describe the current state of knowledge/research regarding effective strategies for the delivery of tobacco cessation training and technical assistance to entities/individuals involved with persons with behavioral health disorders using tobacco.

SECTION B: Proposed Approach (35 points – approximately 4 pages not including Attachment 4 - Project Timeline)

1. Describe the goals and measurable objectives ([see Appendix E](#)) of your proposed project and align them with the Statement of Need outlined in Section A above.
2. Describe how you will implement the Required Activities as stated in [Section I-3](#).
3. In **Attachment 4**, provide a chart or graph depicting a realistic timeline for the entire five years of the project period showing dates, key activities, and responsible staff. These key activities must include the requirements outlined in [Section I-3](#). **[NOTE: The timeline cannot be over two pages and should be submitted in Attachment 4.]** The recommendation of pages for this section does not include the timeline.

SECTION C: Staff, Management, and Relevant Experience (30 points – approximately 3 pages)

1. Describe the experience of your organization with training/TA projects addressing tobacco use by persons with behavioral health disorders. In addition, address how your organization has the specialized skills and expertise to effectively implement the required activities referenced in [Section B](#) above. If you are partnering with other organizations, identify the organizations and describe their experience with similar projects and their specific roles and responsibilities. If applicable, Letters of Commitment from each partner must be included in

Attachment 1 of your application. If you are not partnering with any other organization(s), indicate so in your response.

2. Provide a complete list of staff positions for the project, including the Project Director and other significant staff members, showing the role of each, their level of effort, and qualifications. Describe their specialized experience related to the required activities of this award.

**SECTION D: Data Collection and Performance Measurement
(15 points – approximately 1 pages)**

1. Provide specific information about your how you will collect the required data for this program and how such data will be utilized to manage, monitor, and enhance the program.

**2. BUDGET JUSTIFICATION, EXISTING RESOURCES, OTHER SUPPORT
(Other federal and non-federal sources)**

You must provide a narrative justification of the items included in your proposed budget. You must also provide a narrative description of existing resources and other support you expect to receive for the proposed project as a result of cost matching. Other support is defined as funds or resources, non-federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-federal means. (This should correspond to Item #18 on your SF-424, Estimated Funding.) Other sources of funds may be used for unallowable costs, e.g., meals, sporting events, entertainment.

Although a non-federal share may not be required, if an applicant proposes non-federal resources in their budget, they will be held to submission of the non-federal resources. These must be reported on the financial reports. If recipient fail to meet their proposed amount or percentage, that could be grounds for a cost disallowance.

An illustration of a budget and narrative justification is included in [Appendix L](#) – Sample Budget and Justification. **It is highly recommended that you use this sample budget format.** Your proposed budget must reflect the funding limitations/restrictions specified in [Section IV-5](#). **Specifically identify the items associated with these costs in your budget.**

3. REVIEW AND SELECTION PROCESS

The Project Narratives of SAMHSA applications are peer-reviewed according to the evaluation criteria listed above.

Decisions to fund an award are based on the strengths and weaknesses of the application as identified by peer reviewers. The results of the peer review are advisory in nature.

The program office and approving official make the final determination for funding based on the following;

- When the individual award is over \$250,000, approval by the Center for Mental Health Services and Center for Substance Abuse Treatment National Advisory Councils.
- Availability of funds.
- Submission of any required documentation that must be submitted prior to making an award.
- SAMHSA is required to review and consider any Responsibility/Qualification (R/Q) information about your organization located in SAM.gov. In accordance with 45 CFR 75.212, SAMHSA reserves the right not to make an award to an entity if that entity does not meet the minimum qualification standards as described in section 75.205(a)(2). If SAMHSA chooses not to award a fundable application in accordance with 45 CFR 75.205(a)(2), SAMHSA must report that determination to the designated integrity and performance system accessible through the System for Award Management (SAM) [currently, the Contractor Performance Assessment Reporting System (CPARS)]. You may review and comment on any information about your organization that a federal awarding agency previously entered. SAMHSA will consider your comments, in addition to other information in R/Q in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

VI. FEDERAL AWARD ADMINISTRATION INFORMATION

1. FEDERAL AWARD NOTICES

You will receive an email from SAMHSA, via NIH's eRA Commons, that will describe the process for how you can view the general results of the review of your application, including the score that your application received.

If your application is approved for funding, a Notice of Award (NoA) will be emailed to the following: 1) the BO's email address identified in the Authorized Representative section email field on page 3 of the SF-424; and 2) the email associated with the Commons account for the Project Director (section 8 Item f on page 1 of the SF-424). Hard copies of the NoA will no longer be mailed via postal service. The NoA is the sole obligating document that allows you to receive federal funding for work on the project. Information about what is included in the NoA can be found at: <https://www.samhsa.gov/grants/grants-management/notice-award-noa>.

If your application is not funded, you will receive a notification from SAMHSA, via NIH's eRA Commons.

2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website - . <https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions>. See [Appendix K](#) for specific information about administrative and national policy requirements.

3. REPORTING REQUIREMENTS

You will be required to submit an annual progress report on project performance within 90 days of the end of each budget period. The report must discuss:

- Progress achieved in the project which should include qualitative and quantitative data (GPRA) to demonstrate programmatic progress to include updates on required activities, successes, challenges, and changes or adjustments that have been made to the project.
- Progress addressing quality care of underserved populations related to the Disparity Impact Statement (DIS);
- Barriers encountered, including challenges serving populations of focus;
- Efforts to overcome these barriers;
- Evaluation activities for tracking DIS efforts; and
- A revised quality improvement plan if the DIS does not meet the quality-of-care requirements as stated in the DIS.

A final performance report must be submitted within 120 days after the end of the project period. The final performance report must be cumulative and report on all activities during the entire project period.

Management of Award

Successful applicants must also comply with the following standard award management reporting requirements at <https://www.samhsa.gov/grants/grants-management/reporting-requirements>, unless otherwise noted in the NOFO or NoA.

VII. AGENCY CONTACTS

For program and eligibility questions contact:

Douglas Tipperman
Center for Substance Abuse Prevention, Office of Prevention Innovation
Substance Abuse and Mental Health Services Administration

(240) 276-2442

Douglas.Tipperman@samhsa.hhs.gov

For fiscal/budget questions contact:

Office of Financial Resources, Division of Grants Management

Substance Abuse and Mental Health Services Administration

(240) 276-1400

FOACSAP@samhsa.hhs.gov

For grant review process and application status questions contact:

Hawa Kamara

Office of Financial Resources, Division of Grant Review

Substance Abuse and Mental Health Services Administration

(240) 276-1103

Hawa.kamara@samhsa.hhs.gov

Appendix A – Application and Submission Requirements

1. GET REGISTERED

You are required to complete three **(3) registration processes**:

- 1.1) System for Award Management (SAM);
- 1.2) Grants.gov; and
- 1.3) eRA Commons.

If you have already completed registrations for SAM and Grants.gov, you need to ensure that your accounts are still active, and then register in **eRA Commons (see 1.3)**.

You must register in eRA Commons and receive a Commons Username in order to have access to electronic submission, receive notifications on the status of your application, and retrieve award information.

WARNING: If your organization is not registered and does not have an active eRA Commons PI/PD account by the deadline, the application will not be accepted. No exceptions will be made.

1.1 System for Award Management Registration

You must register your organization with the System for Award Management (SAM). A Unique Entity Identifier (UEI) will be assigned as part of the registration process. (The UEI replaced the Dun and Bradstreet Number (DUNS Number). If your organization is currently registered in SAM.gov, the UEI has already been assigned and is viewable in SAM.gov. This includes inactive registrations. The Unique Entity Identifier is currently located below the DUNS Number on your entity registration record. You must be signed in to your SAM.gov account to view entity records.

You must continue to maintain active SAM registration with current information during the time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)). To create a SAM user account, Register/Update your account, and/or Search Records, go to <https://www.sam.gov>. It takes 7-10 business days for a new SAM entity registration to become active.

It is important to initiate this process well before the application deadline. You will receive an email alerting you when your registration is active.

It is also highly recommended that you renew your account before the expiration date. **SAM information must be active and up-to-date and should be updated at least every 12 months to remain active (for both recipient and sub-recipients).** Once

you update your record in SAM, **it will take 48 to 72 hours to complete the validation processes. Grants.gov rejects electronic submissions from applicants with expired registrations.**

If your SAM account expires, the renewal process requires the same validation with IRS and DoD (Cage Code) as required for a new account.

1.2 Grants.gov Registration

[Grants.gov](http://www.grants.gov) is an online portal for submitting federal award applications. It requires a one-time registration to submit applications. eRA Commons registration is separate but can be done concurrently. You can register to obtain a Grants.gov username and password at <http://www.grants.gov/web/grants/register.html>.

If you have already completed Grants.gov registration and ensured your **Grants.gov and SAM accounts are up-to-date and/or renewed**, go to the eRA Commons registration steps noted below. If this is your first time submitting an application through Grants.gov, registration information can be found at the Grants.gov "[Applicants](#)" tab.

The person submitting your application must be properly registered with Grants.gov as the Authorized Organization Representative (AOR) for the specific UEI number cited on the SF-424 (first page). See the Organization Registration User Guide for details at the following Grants.gov link: <http://www.grants.gov/web/grants/applicants/organization-registration.html>.

1.3 eRA Commons Registration

eRA Commons is an online data platform managed by NIH that allows applicants, award recipient, and federal staff to securely share, manage, and process award-related information. It is strongly recommended that you start the eRA Commons registration process **at least six (6) weeks** before the application due date. Organizations applying for SAMHSA funding must register in eRA Commons. This is a one-time registration separate from Grants.gov registration. Note: Grants.gov and eRA Commons Registration may occur concurrently. In addition to the organization registration, the Business Official (BO) named in the Authorized Representative section field on page 3 of the SF-424 and the Project Director details entered in the Applicant Information item f on page 1 of the SF-424 (Name and contact information of the person to be contacted on matters involving this application) must have accounts in eRA Commons and receive a Commons ID to have access to electronic submission and retrieval of application/award information. **If your organization is not registered and does not have an active eRA Commons PI account by the deadline, the application will not be accepted.**

For organizations registering with eRA Commons for the first time, the BO named in the Authorized Representative section of the SF-424 must complete the [Register Institution](#)

online process. Instructions on how to complete the online Institution Registration Form are provided on the [Register in eRA Commons](#) page.

[Note: You must have a valid and verifiable UEI number to complete the eRA Commons registration.]

After the BO named as the Authorized Representative completes the online Institution Registration Form and clicks Submit, the eRA Commons will send an e-mail notification from era-notify@mail.nih.gov with the link to confirm the email address. Once the e-mail address is verified, the registration request will be reviewed and confirmed via email. If your request is denied, the representative will receive an email detailing the reason for the denial. If the request is approved, the BO will receive an email with an eRA Commons User ID for the Signing Official account (SO) role. The representative will receive a separate email about this SO account containing a temporary password to be used for the first-time log-in. The representative will need to log into eRA Commons with the temporary password, at which time the system will provide prompts to change the temporary password to one of their choosing. Once the BO/SO signs the registration request, the organization will be active in eRA Commons. The BO/SO can then create additional accounts for the organization as needed. Organizations can have multiple user accounts with the SO role, and any user with the SO role will be able to create and maintain additional accounts for the organization's staff, including accounts for those designated as Project Director/Principal Investigator (PD/PI) and other Signing Officials.

Important: The eRA Commons requires organizations to identify at least one BO/SO, who is the BO entered in the Authorized Representative section on the SF-424, and a PD/PI to submit an application. The primary BO/SO must create the account for the PD/PI listed as the person to contact regarding the application on page 1 of the SF-424 assigning that person the 'PI' role in eRA Commons. Note that you must also enter the PD/PI's Commons Username into the 'Applicant Identifier' field of the SF-424 document (Line 4). **The individual designated as the BO cannot also be a PD.**

2. WRITE AND COMPLETE THE APPLICATION

SAMHSA strongly encourages you to sign up for Grants.gov email notifications regarding this NOFO. If the NOFO is cancelled or modified, individuals who sign up with Grants.gov for updates will be automatically notified.

2.1 Obtaining Paper Copies of Application Materials

If your organization has difficulty accessing high-speed internet and cannot download the required documents, you may request a paper copy of the application materials. Contact the Division of Grant Review at dgr.applications@samhsa.hhs.gov for additional information on obtaining paper copies.

2.2 Required Application Components

After downloading and retrieving the required application components and completing the registration processes, it is time to write and complete your application. All files uploaded with the Grants.gov application **MUST** be in **Adobe PDF** file format. Directions for creating PDF files can be found on the Grants.gov website. See [Appendix B](#) for all application formatting and validation requirements.

Standard Application Components

Applications must include the following required application components listed in the table below. This table consists of a full list of standard application components, a description of each required component, and where you can find each document.

#	Standard Application Components	Description	Where to Find Document
1	SF-424 (Application for Federal Assistance) Form	<p>This form must be completed by applicants for all SAMHSA awards. The names and contact information for Project Director (PD) and Business Official (BO) are required for SAMHSA applications and are to be entered on the SF-424 form.</p> <ul style="list-style-type: none"> The PD must have an eRA Commons account: the PD's Commons Username must be entered in field 4. Applicant Identifier; and the PD's name, phone number and email address must be entered in Section 8. APPLICANT INFORMATION: item f. Name and contact information of person to be contacted on matters involving this application. <u>The PD listed in the SF-424 must match the PD in the Personnel Costs section in the budget.</u> The BO name, title, email address and phone number must be entered in the Authorized Representative section fields on page three of the SF 424. The organization mailing address is required in section 8. APPLICANT INFORMATION item d. Address. <p>All SAMHSA Notices of Award (NoAs) will be emailed by SAMHSA via NIH's eRA Commons to the Project Director/Principal Investigator (PD/PI), and the Signing Official/Business Official (SO/BO).</p>	Grants.gov/forms
2	SF-424 A (Budget Information – Non-Construction Programs) Form	Use SF-424A. Fill out Sections A, B, D and E of the SF-424A. Section C should only be completed if applicable. It is highly recommended that you use the budget template. (See Section IV.2)	Grants.gov/forms

#	Standard Application Components	Description	Where to Find Document
3	Project/Performance Site Location(s) Form	The purpose of this form is to collect physical location information on the site(s) where work funded under this announcement will be performed. The address cannot be a P.O. Box.	Grants.gov/forms
4	Project Abstract Summary	It is recommended the abstract is no more than one page. It should include the project name, population(s) to be served (demographics and clinical characteristics), strategies/interventions, project goals and measurable objectives, including the number of people to be served annually and throughout the lifetime of the project, etc. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reports to Congress, or press releases.	
5	Project Narrative Attachment	The Project Narrative is your response to the Evaluation Criteria found at Section V.1 of this NOFO. It cannot be longer than 10 pages. You must attach the Project Narrative file (Adobe PDF format only) inside the Project Narrative Attachment Form.	
6	Budget Justification and Narrative Attachment	You must include a detailed Budget Narrative in addition to Budget Form SF-424A. In preparing the budget, adhere to any existing federal award or agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. The budget justification and narrative must be submitted as file name " BNF " when you submit your application into Grants.gov.	SAMHSA Website
7	SF-424 B (Assurances for Non-Construction) Form	You must read the list of assurances provided on the SAMHSA website and check the box marked 'I Agree' before signing the first page (SF-424) of the application.	SAMHSA Website
8	Disclosure of Lobbying Activities (SF-LLL) Form	Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. For SAMHSA to determine whether or not your organization participates in lobbying activities, a signed copy of the SF-LLL form must be submitted. If your organization does not participate in lobbying activities, indicate "Not Applicable" on the form.	Grants.gov/forms

#	Standard Application Components	Description	Where to Find Document
9	Other Attachments Form	Refer to the Supporting Documents below. Use the Other Attachments Form to attach all required additional/supporting documents listed in the table below.	

Supporting Documents

In addition to the Standard Application Components listed above, the following supporting documents are necessary for the review of your application. Supporting documents must be attached to your application. **For each of the following application components, attach each document (Adobe PDF format only) using the Other Attachments Form in ASSIST, Workspace, or other S2S provider.**

#	Supporting Documents	Description	Where to Find Document
1	HHS 690 Form	Every applicant must have a completed HHS 690 form (PDF 291 KB) on file with the Department of Health and Human Services.	SAMHSA Website
2	Biographical Sketches and Job Descriptions (Attachment 5)	See Appendix G of this document for additional instructions for completing these sections. Formatting requirements outlined in Appendix B are not applicable for these documents.	Appendix G of this document.
3	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 7)	See the NOFO for requirements related to confidentiality, participant protection, and the protection of human subject's regulations.	Appendix D of this document.
4	Additional Documents in the NOFO	The NOFO will indicate the attachments you need to include in your application.	NOFO: Section IV.

2.3 Additional Documents for Submission (SAMHSA Website)

You will find additional materials you will need to complete your application on the SAMHSA website at <http://www.samhsa.gov/grants/applying/forms-resources>.

3. SUBMIT APPLICATION

3.1 Electronic Submission (eRA ASSIST, Grants.gov Workspace, or other S2S provider)

After completing all required registration and application requirements, SAMHSA requires applicants to **electronically submit** using eRA ASSIST, Grants.gov Workspace, or another system to system (S2S) provider. Information on each of these options is below:

- 1) **ASSIST** – The Application Submission System and Interface for Submission Tracking (ASSIST) is an NIH sponsored online interface used to prepare applications using the SF-424 form set, submit electronically through Grants.gov to SAMHSA and other participating agencies, and track applications. [Note: ASSIST requires an eRA Commons ID to access the system]
- 2) **Grants.gov Workspace** – You can use the shared, online environment of the Grants.gov Workspace to collaboratively work on different forms within the application.

The specific actions you need to take to submit your application will vary by submission method as listed above. The steps to submit your application are as follows:

To submit to Grants.gov using ASSIST: [eRA Modules, User Guides, and Documentation | Electronic Research Administration \(eRA\)](#)

To submit to Grants.gov using the Grants.gov Workspace:

<http://www.grants.gov/web/grants/applicants/workspace-overview.html>

Regardless of the option you use, your application will be subject to the same registration requirements, completed with the same data items, routed through Grants.gov, validated against the same agency business rules, assembled in a consistent format for review consideration, and tracked in eRA Commons. All applications that are successfully submitted must be validated by Grants.gov before proceeding to the NIH eRA Commons system and validations.

3.2 Waiver from Electronic Submission

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver of this requirement in advance.

If you do not have the technology to apply online, or your physical location has no Internet connection, you may request a waiver of electronic submission. **You must send a written request to the Division of Grant Review at least 15 calendar days before the application due date.**

Direct any questions regarding the submission waiver process to the Division of Grant Review at dgr.applications@samhsa.hhs.gov.

3.3 Deadline

On-time submission requires that electronic applications be error-free and made available to SAMHSA for processing from the NIH eRA system on or before the application due date and time. Applications must be submitted to and validated successfully by Grants.gov and eRA Commons no later than 11:59 PM Eastern Time on the application due date. Applications submitted in Grants.gov after the application due date will not be considered for review.

You are strongly encouraged to allocate additional time prior to the submission deadline to submit your application and to correct errors identified in the validation process. You are also encouraged to check the status of your application submission to determine if the application is complete and error-free.

3.4 Resources for Assistance

If you encounter problems when submitting your application in Grants.gov, you must attempt to resolve them by contacting the Grants.gov Service Desk at the following:

- By e-mail: support@grants.gov
- By phone: (toll-free) 1-800-518-4726 (1-800-518-GRANTS). The Grants.gov Contact Center is available 24 hours a day, 7 days a week, excluding federal holidays.

Make sure you receive a case/ticket/reference number that documents the issues/problems with Grants.gov.

Additional support is also available from the NIH eRA Service desk at:

- To submit a service request ticket: <http://grants.nih.gov/support/index.html>
- By phone: 301-402-7469 or (toll-free) 1-866-504-9552. (Press menu option 6 for SAMHSA). The NIH eRA Service desk is available Monday – Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

If you experience problems accessing or using ASSIST (see below), you can:

- Access the ASSIST Online Help Site at: <https://era.nih.gov/erahelp/assist/>
- Or contact the NIH eRA Service Desk

SAMHSA highly recommends that you submit your application 24-72 hours before the submission deadline. Many submission issues can be fixed within that time and you can attempt to re-submit.

4. AFTER SUBMISSION

4.1 System Validations and Tracking

After you complete and comply with all registration and application requirements and submit your application, the application will be validated by Grants.gov. You will receive a notification that your application is being processed. You will receive two additional e-mails from Grants.gov within the next 24-48 hours (one notification email will confirm receipt of the application in Grants.gov, and the other notification email will indicate that the application was either successfully validated by the Grants.gov system or rejected due to errors). It is important that you retain this Grants.gov tracking number. **Receipt of the Grants.gov tracking number is the only indication that Grants.gov has successfully received and validated your application. If you do not receive a Grants.gov tracking number, you may want to contact the Grants.gov help desk for assistance (see Resources for Assistance in Section 3.4).**

If Grants.gov identifies any errors and rejects your application with a “Rejected with Errors” status, you must address all errors and resubmit. If no problem is found, Grants.gov will allow the eRA system to retrieve the application and check it against its own agency business rules (eRA Commons validations). If you use ASSIST to complete your application, you can validate your application and fix errors before submission.

After you successfully submit your application through Grants.gov, your application will go through eRA Commons validations. If no errors are found, the application will be assembled in eRA Commons. At this point, you can view your application in eRA Commons. It will then be forwarded to SAMHSA as the receiving institution for further review.

If errors are found during eRA Commons validation, you will receive a System Error and/or Warning notification regarding the problems found in the application (see 4.2 below). You must take action to make the required corrections and resubmit the application through Grants.gov before the application due date and time (**See 4.4 below**). Do not assume that if your application passes the Grants.gov validations that it will successfully pass eRA validations and will be received by SAMHSA. You must check your application status in eRA Commons to ensure that no errors were identified. It is critical that you allow for sufficient time to resubmit the application if errors are detected.

You are responsible for viewing and tracking your applications in the eRA Commons after submission through Grants.gov to ensure accurate and successful submission. Once you can access your application in the eRA Commons, be sure to review it carefully as this is what reviewers will see.

4.2 eRA Commons: Warning vs. Error Notifications

You may receive a System Warning and/or Error notification after submitting an application. Take note that there is a distinction between System Errors and System Warnings.

Warnings – If you receive a Warning notification after the application is submitted, you are not required to resubmit the application. The reason for the Warning will be identified in the notification. It is at your discretion to choose to resubmit, but if the application was successfully received, it does not require any additional action.

Errors – If you receive an Error notification after the applications is submitted, you must correct and resubmit the application. The word Error is used to characterize any condition which causes the application to be deemed unacceptable for further consideration.

4.3 System or Technical Issues

If you encounter a system error that prevents you from completing the application submission process on time, the BO from your organization will receive an email notification from eRA Commons. SAMHSA highly recommends contacting the eRA Service Desk and submitting a web ticket to document your good faith attempt to submit your application and determining next steps. See Section 3.4 for more information on contacting the eRA Service Desk.

4.4 Resubmitting a Changed/Corrected Application

If SAMHSA does not receive your application by the application due date as a result of a failure in the SAM, Grants.gov, or NIH's eRA Commons systems, you must contact the Division of Grant Review within **one business day after the official due date at: dgr.applications@samhsa.hhs.gov** and provide the following:

- A case number or email from SAM, Grants.gov, and/or NIH's eRA system that allows SAMHSA to obtain documentation from the respective entity for the cause of the error.

SAMHSA will consider the documentation to determine **if** you followed Grants.gov and NIH's eRA requirements and instructions, met the deadlines for processing paperwork within the recommended time limits, met NOFO requirements for submission of electronic applications, and made no errors that caused submission through Grants.gov or NIH's eRA to fail. No exceptions for submission are allowed when user error is involved. Note that system errors are extremely rare.

[Note: When resubmitting an application after revisions have been made, ensure that the **Project Title is identical to the Project Title in the originally submitted application** (i.e., no extra spacing) as the Project Title is a free-text form field.] In addition, check the Changed/Corrected Application box in #1.

Appendix B - Formatting Requirements and System Validation

1. SAMHSA FORMATTING REQUIREMENTS

SAMHSA's goal is to review all applications submitted for funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. See below for a list of formatting requirements required by SAMHSA:

- Text must be legible. Pages must be typed in black, single-spaced, using a font of Times New Roman 12, with all margins (left, right, top, bottom) at least one inch each. You may use Times New Roman 10 only for charts or tables.
- **You must submit your application and all attached documents in Adobe PDF format, or your application will not be forwarded to eRA Commons and will not be reviewed. See Section 3 below for more details on PDF requirements.**
- To ensure equity among applications, the 10-page limit for the Project Narrative cannot be exceeded. If an application exceeds the 10-page limit, the application will not be reviewed.
- Citations can be put in an Attachment. They do not have to be placed in the Project Narrative.
- Black print should be used throughout your application, including charts and graphs (no color).
- If you are submitting more than one application under the same announcement number, you must ensure that the Project Title in Field 15 of the SF-424 is unique for each submission.

2. GRANTS.GOV FORMATTING AND VALIDATION REQUIREMENTS

- Grants.gov allows the following list of UTF-8 characters when naming your attachments: A-Z, a-z, 0-9, underscore, hyphen, space, and period. Other UTF-8 characters should not be used as they will not be accepted by NIH's eRA Commons, as indicated in item #9 in the table below.
- Scanned images must be scanned at 150-200 dpi/ppi resolution and saved as a PDF file. Using a higher resolution setting or different file type will result in a larger file size, which could result in rejection of your application.

- Any files uploaded or attached to the Grants.gov application must be PDF file format and must contain a valid file format extension in the filename. In addition, the use of compressed file formats such as ZIP, RAR or Adobe Portfolio will not be accepted.

3. eRA COMMONS FORMATTING AND VALIDATION REQUIREMENTS

The following are formatting requirements and system validations required by eRA Commons and will result in errors if not met. The application must be 'error free' to be processed through the eRA Commons. There may be additional validations which will result in Warnings but these will not prevent the application from processing through the submission process. (See Appendix A, Section 4.2)

ASSIST File Formatting Requirements

The eRA system contains file formatting requirements for uploading documents in ASSIST. The only accepted file type for submission is PDF and each file may be no larger than 6 MB. Fillable forms must be 'flattened' and saved as a PDF prior to upload. Adobe Portfolio file types will not be accepted.

Files for Upload to ASSIST must be:

- PDF Format
- Under 6MB in File Size
- 8.5 x 11 Page Size
- Flat (*No Fillable/Editable Fields*)

Files must **NOT** contain:

- Password-Protection
- Live hyperlinks (*only plain text URLs*)
- Bookmarks or Signature Boxes
- A filename exceeding 50 Characters (*including spaces*)

Flatten Fillable Forms Prior to Upload in ASSIST

A completed fillable form (an electronic document that can be filled out and edited digitally—also called fillable, dynamic, or interactive forms) should not only be saved as a PDF; it must also be flattened to remove the interactive fields so that the final answers are saved. Flattening a form is not the same as "locking" it; locking a form restricts access to editing, printing, and copying the document.

Flattening a PDF document:

- **Keeps form values permanent.** When an interactive PDF is uploaded or emailed, every field remains open to accidental or deliberate revision. Flattening the form ensures that only the completed version of the form is visible.
- **Removes values on drop down lists.** A flattened document will show only the selected text or value, no other values and options are shown and there is no indication that options were present.
- **Simplifies the PDF.** Interactive forms are larger than normal files, which may prevent upload for submission. Flattening reduces the file size which makes it easier to render and view.

To flatten a file, follow the steps below.

1. Ensure that the form is completed and the information is correct. Go to the print settings by selecting **File > Print**.
2. On the pull-down menu of printer options, choose Adobe PDF or Microsoft Print to PDF, then click OK.
3. After clicking **OK**, a pop-up will open with options to save the PDF. Be sure to select a specific location to save the document where it can easily be found and give it a unique file name. Use a file name that clearly differentiates the completed form from the original fillable form. File names cannot exceed 50 characters.
4. The flattened form should appear in the new location with the new file name. Open it to check once more for any changes and to confirm that the conversion worked.

If you do not adhere to these requirements, you will receive an email notification from era-notify@mail.nih.gov to take action and adhere to the requirements so that your application can be processed successfully. It is highly recommended that you submit your application 24-72 hours before the submission deadline to allow for sufficient time to correct errors and resubmit the application. If you experience any system validation or technical issues after hours on the application due date, contact the eRA Service Desk and submit a Web ticket to document your good faith attempt to submit your application.

eRA Commons Validation Table

The following table shows formatting requirements and system validations required by eRA Commons and will result in errors if not met.

eRA Validations	eRA Error Messages
<p>#1: Applicant Identifier (Item 4 on the SF-424):</p> <p>The PD/PI Credentials must be provided</p> <p>Username provided must be a valid Commons account</p> <p>Username must be affiliated with the organization submitting the application and/or have the PI role</p>	<p>The Commons Username must be provided in the Applicant Identifier field for the PD/PI.</p> <p>The Commons Username provided in the Applicant Identifier is not a recognized Commons account.</p> <p>The Commons account provided in the Applicant Identifier field for the PD/PI is either not affiliated with the applicant organization or does not hold the PI role. Check with your Commons Account Administrator to make sure your account affiliation and roles are set-up correctly.</p>
<p>#2. The UEI number provided must include valid characters (12 numbers)</p>	<p>The UEI number provided has invalid characters (other than 12 numbers)</p>
<p>#3. The documentation (forms) required for the NOFO must be submitted</p>	<p>The format of the application does not match the format of the NOFO. Contact the eRA Service Desk for assistance.</p>
<p>#4. If a change or correction is made to address an error, "Changed/Corrected" must be selected. (Item #1 on the SF-424). Refer to Appendix A II-4.4 for more information on resubmission criteria.</p>	<p>This application has been identified as a duplicate of a previous submission. The 'Type of Submission' should be set to Changed/Corrected if you are addressing errors/warnings.</p>
<p>#5. The application cannot exceed 1.2GB.</p>	<p>The application did not follow the agency-specific size limit of 1.2 GB. Resize the application to be no larger than 1.2 GB before submitting.</p>
<p>#6. The correct Notice of Funding Opportunity (NOFO) number must be provided</p>	<p>The Funding Opportunity Announcement number does not exist.</p>
<p>#7. All documents and attachments must be submitted in PDF format.</p>	<p>"The <attachment> attachment is not in PDF format. All attachments must be provided to the agency in PDF format with a .pdf extension. Help with PDF attachments can be found at http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm."</p>
<p>#8. All attachments must comply with the following formatting requirements: PDF attachments cannot be empty (0 bytes).</p> <p>All PDF attachments cannot have Meta data missing, cannot be encrypted, password protected or secured documents.</p>	<p>The {attachment} attachment was empty. PDF attachments cannot be empty, password protected or encrypted.</p> <p>The <attachment> attachment contained formatting or features not currently supported by NIH: <condition returned>.</p>

eRA Validations	eRA Error Messages
<p>The size of PDF attachments cannot be larger than 8.5 x 11 inches (horizontally or vertically). [Note: It is recommended that you limit the size of attachments to 35 MB.]</p> <p>PDF attachments must have a valid file name. Valid file names must include the following UTF-8 characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.</p>	<p>Filename <file> cannot be larger than U.S. standard letter paper size of 8.5 x 11 inches. See the PDF guidelines at http://grants.nih.gov/grants/ElectronicReceipt/pdf/guidelines.htm</p> <p>The <attachment> attachment filename is invalid. Valid filenames may only include the following characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, or period. No special characters (including brackets) can be part of the filename.</p>
<p>#9. The email addresses for the Contact Person (SF-424 Section F) and the Authorized Representative (SF-424 below Section 21) must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > () [] \ , ; : are not valid.</p>	<p>The submitted e-mail address for the person to be contacted {email address}, is invalid. Must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > () [] \ , ; : are not valid.</p>
<p>#10. Congressional district code of applicant (after truncating) must be valid. (SF-424, item 16 a and b)</p>	<p>Congressional district <Congressional District> is invalid. To locate your district, visit http://www.house.gov/</p>

Budget Errors	
eRA Validations	eRA Error Messages
<p><u>SF424-A: Section A – Budget Summary</u> The total fields at the end of rows or at the bottom of columns must equal the sum of the elements for that row or column</p>	<p>Ensure that the sum of Grant Program Function or Activity (a) elements entered equals the total amounts in the Total field</p>
<p><u>SF424-A: Section B – Budget Categories</u> The Total in Section B (Column 5 - Row k) must equal the Total in Section A – Budget Summary: (Row 5, Column g).</p>	<p>Ensure that the TOTALS Total (row k, column 5) equals the Budget Summary Totals in section A, row 5 column g.</p>
<p><u>SF424-A: Section D – Forecasted Cash Needs</u> The Federal Total for the 1st Year (Line 13) must equal the Total in Section A (Row 5, Column g)</p> <p>The Non-Federal Total for 1st Year sum must equal Estimated Unobligated Funds Non-Federal Totals in Section A (d-5) + New or Revised Budget Non-Federal Totals (f-5)</p>	<p>Ensure that the Federal Total for 1st year, in Section D- Forecasted Needs equals the Section A, New or Revised Budget Federal Totals (e-5) amount.</p> <p>Ensure that the Non-Federal Total for 1st year equals the sum of Estimated Unobligated Funds Non-Federal Totals (d-5) and New or Revised Budget Non-Federal Totals (f-5) on Section A.</p>
<p>The Total for 1st Year TOTAL in Section D must equal the Total (Row 5, Column G) in Section A</p>	<p>Ensure that the Forecasted Cash Needs: 15 TOTAL equals to SECTION A – Budget Summary: Line 5. Totals, Column (g).</p>
<p><u>SF424-A: Section E – Budget Estimates of Federal Funds Needed for Balance of The Project</u></p> <p>The number of budget years/periods must match the span of the project. The number of years in the project period in Block 17 on the SF-424 must align with the future funding periods.</p>	<p>Ensure that the project period years on the SF 424 block 17 matches the provided budget periods in the SF-424A. Enter data for the first budget period in Section D and enter future budget periods in Section E.</p>

Appendix C – General Eligibility Information

Determining whether you are eligible to apply for and receive a SAMHSA award is very important. If you are not legally eligible for a specific funding opportunity, you would spend considerable time and money completing the application process when you cannot receive the award.

There are many types of organizations generally eligible to apply for SAMHSA funding opportunities. However, eligibility is strictly tied to the statutory authority governing this award. Please be sure to double check the NOFO for eligibility. Eligibility for this NOFO may include the following:

Government Organizations

- State governments and territories
- County governments
- City or township governments
- Special district governments
- Native American tribal governments (federally recognized)
- Native American tribal governments (other than federally recognized)
- State-Recognized Tribes

Other Tribal Entities

- Tribal organizations
- Consortia of tribes or tribal organizations
- Urban Indian Organizations

Education Organizations

- Independent school districts
- Public and state-controlled institutions of higher education
- Private institutions of higher education
- Education agencies/authorities serving children and youth residing in federally recognized American Indian/Alaska Native (AI/AN) tribes

Non-profit Organizations

- Non-profits having a 501(c)(3) status with the Internal Revenue Service (IRS), other than institutions of higher education
- Non-profits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education, including entities with 501(c)(4) status (civic leagues, social welfare organizations, and local associations of employees) and 501(c)(5) status (labor organizations).

Please note: For-profit organizations and foreign entities are not eligible to apply for SAMHSA awards.

Appendix D – Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines

CONFIDENTIALITY AND PARTICIPANT PROTECTION:

It is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. **As part of Attachment 7 of the application, all applicants (including those who plan to obtain Institutional Review Board (IRB) approval) must address all of the elements below.** If some elements are not applicable to the proposed project, explain why the element(s) is not applicable.

In addition to addressing these elements, you will need to determine if the section below titled “Protection of Human Subjects Regulations” applies to your project. If so, you must submit the required documentation as described below. There are no page limits for your response to the elements in this appendix.

1. Protect Participants and Staff from Potential Risks

- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **participants** may be exposed to because of the project.
- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects **staff** may be exposed to as a result of the project.
- Describe the procedures you will follow to minimize or protect participants and staff against potential risks, including risks to confidentiality.
- Identify your plan to provide guidance and assistance in the event there are adverse effects to participants and/or staff.

Responses that will be considered unacceptable or incomplete:

- *Indicating that there are **no risks** to participants. If services are being delivered as part of the project, it is **very unlikely** that there will be no foreseeable physical, medical, psychological, social, or legal risks or potential adverse effects as a result of their involvement in the project.*
- *Addressing potential risks to participants but not addressing risks to staff*
- *Neglecting to describe how the organization will provide guidance and assistance in the event there are adverse effects to participants and whether alternative treatments will be available to participants.*

2. Fair Selection of Participants

- Explain how you will recruit and select participants ensuring all populations have equitable opportunities to participate in the program.
- Identify any individuals in the geographic catchment area where services will be delivered who will be excluded from participating in the project and explain the reasons for this exclusion.

Responses that will be considered unacceptable or incomplete:

- *Not explaining reasons for including or excluding participants*
- *Not identifying how participants will be selected*

3. Absence of Coercion

- If you plan to compensate participants, state how participants will be awarded incentives (e.g., gift cards, bus passes, gifts, etc.) If you plan to implement a contingency management program, specify the evidence-based model you will use and briefly justify its use with your population(s) of focus. If you have included funding for incentives in your budget, you **must** address this item. (For specific information about incentives, see <https://www.samhsa.gov/grants/grants-management/policies-regulations/additional-directives>)
- Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an “undue inducement” that removes the voluntary nature of participation.
- Describe how you will inform participants in a culturally competent manner that they may receive services even if they choose to not participate in or complete the data collection component of the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating that you do not plan to compensate participants, such as through incentives, but including funding for incentives in the budget or describing the use of incentives in the Project Narrative.*
- *Not specifying how participants will be told that they may receive services even if they choose not to participate in the data collection component of the project*

4. Data Collection

- Identify from whom you will collect data (e.g., participants, clients, family members, teachers, others).
- Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation, or other sources). Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the specimens will be used for purposes other than evaluation.
- In **Attachment 2**, “Data Collection Instruments/Interview Protocols,” you **must** provide copies of all available data collection instruments and interview protocols that you plan to use (unless you are providing the web link to the standardized instrument(s)/protocol(s). Include any culturally adapted data collection instruments and interview protocols.

Responses that will be considered unacceptable or incomplete:

- *Not clearly identifying all the entities from which data will be collected.*
- *Describing the use of drug testing in the Project Narrative but not providing the requested information about specimen collection.*
- *Not including data collection instruments/interview protocols (or links to websites for the instruments) in Attachment 2*
- *Not including how the data collection will occur (i.e., paper surveys versus electronic survey links; at a school setting or at the organization’s clinic, etc.).*

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Describe:
 - Where data will be stored,
 - Who will have access to the data collected, and
 - How the identity of participants will be kept private, for example, using a coding system on data records, limiting access to records, or storing identifiers separately from data.
 - **NOTE:** Recipient must maintain the confidentiality of substance use disorder client records according to the provisions of **Title 42 of the Code of Federal Regulations, Part II, Subpart B.**

Responses that will be considered unacceptable or incomplete:

- *Not providing detailed information about where data is stored and how the identity of participants will be kept confidential.*
- *Not clearly identifying the individuals who will have access to the data.*
- *Not specifying that you agree to maintain the confidentiality substance use disorder client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.*

6. Adequate Consent Procedures

- Include, as appropriate, sample consent forms* that provide for:
 1. informed consent for participation in service intervention;
 2. informed consent for participation in the data collection component of the project, including information that participants are informed that they may receive services even if they choose not to participate in or complete this component of the project; and
 3. informed consent for the exchange (releasing or requesting) of confidential information.
 4. Informed consent for youth participants.

*Consent forms should be written at no higher than 8th grade reading level.

- The sample forms must be included in **Attachment 3, “Sample Consent Forms”**, of your application. If needed, provide translated forms.
- Explain how you will obtain consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

NOTE: The consent forms should never imply that the participant waives or appears to waive any legal rights. The forms should also not imply that individuals cannot end involvement with the project or that your project or its agents will be released from liability for negligence.

Responses that will be considered unacceptable or incomplete:

- *Not providing copies of sample consent forms in Attachment 3*
- *Not providing details on how consent/assent will be obtained for youth participants.*

- *Not providing details on how consent will be obtained for non-English speaking priority populations identified in the application.*

7. Risk/Benefit Discussion

- Discuss why the risks you have identified in **Element 1. Protect Participants and Staff from Potential Risks** are reasonable compared to the anticipated benefits to participants involved in the project.

Responses that will be considered unacceptable or incomplete:

- *Indicating there are no risks to participants in the first element and noting that this element is therefore not applicable.*
- *Not mentioning any anticipated benefits to participants involved in the project.*

PROTECTION OF HUMAN SUBJECTS REGULATIONS

SAMHSA expects that most recipients funded under this announcement will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval. However, in some instances, the applicant's proposed project may meet the regulation's criteria for research involving human subjects. Although IRB approval is not required at the time of award, you are required to provide the documentation below prior to enrolling participants into your project.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must:

- Describe the process for obtaining IRB approval for your project.
- Provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP).
- Provide documentation that IRB approval has been obtained for your project prior to enrolling participants.

General information about Human Subjects Regulations can be obtained through OHRP at <http://www.hhs.gov/ohrp> or (240) 453-6900. SAMHSA-specific questions should be directed to the program contact listed in Section VII of this announcement.

Appendix E – Developing Goals and Measurable Objectives

To be able to effectively evaluate your project, it is critical that you develop realistic goals and measurable objectives. This appendix provides information on developing goals and objectives for use in your Project Narrative. It also provides examples of well-written goals and measurable objectives.

GOALS

Definition – a goal is a broad statement about the long-term expectation of what should happen because of your program (the desired result). It serves as the foundation for developing your program objectives. Goals should align with the statement of need that is described. Goals should only be one sentence.

The characteristics of effective goals include:

- Goals address outcomes, not how outcomes will be achieved.
- Goals describe the behavior or condition in the community expected to change.
- Goals describe who will be affected by the project.
- Goals lead clearly to one or more measurable results.
- Goals are concise.

Examples

Unclear Goal	Critique	Improved Goal
Increase the substance use and HIV/AIDS prevention capacity of the local school district	This goal could be improved by <i>specifying an expected program effect in reducing a health problem</i>	Increase the capacity of the local school district to reduce high-risk behaviors of students that may contribute to substance use and/or HIV/AIDS
Decrease the prevalence of marijuana, alcohol, and prescription drug use among youth in the community by increasing the number of schools that implement effective policies, environmental change, intensive training of teachers, and educational approaches to address high-risk behaviors, peer pressure, and tobacco use.	This goal is not concise	Decrease youth substance use in the community by implementing evidence-based programs within the school district that address behaviors that may lead to the initiation of use.

OBJECTIVES

Definition – Objectives describe the results to be achieved and the manner in which they will be achieved. Multiple objectives are generally needed to address a single goal. Well-written objectives help set program priorities and targets for progress and accountability. It is recommended that you avoid verbs that may have vague meanings to describe the intended outcomes, like “understand” or “know” because it may prove difficult to measure them. Instead, use verbs that document action, such as: “By the end of 2020, 75% of program participants will be *placed* in permanent housing. To be effective, objectives should be clear and leave no room for interpretation.

SMART is a helpful acronym for developing objectives that are ***specific, measurable, achievable, realistic, and time-bound***:

Specific –

Includes the “who” and “what” of program activities. Use only one action verb to avoid issues with measuring success. For example, “Outreach workers will administer the HIV risk assessment tool to at least 100 injection drug users in the population of focus” is a more specific objective than “Outreach workers will use their skills to reach out to drug users on the street.”

Measurable –

How much change is expected. It must be possible to count or otherwise quantify an activity or its results. It also means that the source of and mechanism for collecting measurement data can be identified and that collection of the data is feasible for your program. A baseline measurement is required to document change (e.g., to measure the percentage of increase or decrease). If you plan to use a specific measurement instrument, it is recommended that you incorporate its use into the objective. Example: By 9/20 increase by 10% the number of 8th, 9th, and 10th grade students who disapprove of marijuana use as measured by the annual school youth survey.

Achievable –

Objectives should be attainable within a given time frame and with available program resources. For example, “The new part-time nutritionist will meet with seven teenage mothers each week to design a complete dietary plan” is a more achievable objective than “Teenage mothers will learn about proper nutrition.”

Realistic –

Objectives should be within the scope of the project and propose reasonable programmatic steps that can be implemented within a specific time frame. For example, “Two ex-gang members will make one school presentation each week for two months to raise community awareness about the presence of gangs” is a more realistic objective than “Gang-related violence in the community will be eliminated.”

Time-bound –

Provide a time frame indicating when the objective will be measured or a time by when the objective will be met. For example, “Five new peer educators will be recruited by

the second quarter of the first funding year” is a better objective than “New peer educators will be hired.”

Examples:

Non-SMART Objective	Critique	SMART Objective
<p>Teachers will be trained on the selected evidence-based substance use prevention curriculum.</p>	<p>The objective is not SMART because it is not <i>specific</i>, <i>measurable</i>, or <i>time-bound</i>. It can be made SMART by <i>specifically</i> indicating who is responsible for training the teachers, how many will be trained, who they are, and by when the trainings will be conducted.</p>	<p><i>By June 1, 2022, LEA supervisory staff</i> will have trained <i>75% of health education teachers in the local school district</i> on the selected, evidence-based substance use prevention curriculum.</p>
<p>90% of youth will participate in classes on assertive communication skills.</p>	<p>This objective is not SMART because it is not <i>specific</i> or <i>time-bound</i>. It can be made SMART by indicating <i>who</i> will conduct the activity, <i>by when</i>, and <i>who</i> will participate in the lessons on assertive communication skills.</p>	<p>By the <i>end of the 2022 school year, district health educators</i> will have conducted classes on assertive communication skills for 90% of youth <i>in the middle school</i> receiving the <i>substance use and HIV prevention curriculum</i>.</p>
<p>Train individuals in the community on the prevention of prescription drug/opioid overdose-related deaths.</p>	<p>This objective is not SMART as it is not <i>specific</i>, <i>measurable</i> or <i>time-bound</i>. It can be made SMART by specifically indicating <i>who</i> is responsible for the training, <i>how many</i> people will be trained, <i>who</i> they are, and by <i>when</i> the training will be conducted.</p>	<p><i>By the end of year two of the project, the Health Department</i> will have trained <i>75% of EMS staff in the County Government</i> on the selected curriculum addressing the prevention of prescription drug/opioid overdose-related deaths.</p>

Appendix F – Developing the Plan for Data Collection and Performance Measurement

Information in this Appendix should be taken into consideration when developing a response for criteria in Section D of the Project Narrative.

Data Collection:

In describing your plan for data collection, consider addressing the following points:

- Electronic data collection software that will be used
- Frequency of data collection
- Organizational processes that will be implemented to ensure the accurate and timely collection and input of data.
- Staff that will be responsible for collecting and recording the data.
- Data source and data collection instruments that will be used to collect the data.
- How well the data collection methods will take into consideration the language, norms, and values of the population(s) of focus.
- Processes and policies to keep data secure.
- If applicable, how will the data collection procedures ensure that confidentiality is protected and that informed consent is obtained.
- If applicable, data collection procedures from partners and/or sub-recipients.

It is not necessary to provide information related to data collection and performance measurement in a table, but the following samples may give you some ideas about how to display the information.

Table 1 [provides an example of how information for the required performance measures could be displayed]

Performance Measures	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis

Table 2 [provides an example of how information could be displayed for the data that will be collected to measure the objectives that are included in B.1]

Objective	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis
Objective 1.a				
Objective 1.b				

Data Management and Performance Monitoring

Points to consider:

- Data protection policies and procedures, including information about storage, retention, and access.
- Frequency of reviews and monitoring of performance data.
- Staff conducting data analysis, including evaluation.
- Data analysis methods and how you will use data to monitor and evaluate activities and processes.
- Staff responsible for completing reports.
- How data will be reported to staff, stakeholders, SAMHSA, an Advisory Board, and other relevant project partners.

How Data Will Be Used to Enhance the Project/Quality Improvement (QI):

Points to consider:

- If applicable, the QI model that will be used.
- How will the QI process be used to track progress?
- Staff responsible for overseeing these QI processes.
- Details of how you plan to implement any needed changes to project implementation and/or project management.
 - What decision-making processes will be used?
 - When and by whom will decisions be made concerning project improvement?
 - What are the thresholds for determining that changes need to be made?
 - Will the Advisory Board have a role in the QI process?
 - How will the changes be communicated to staff and/or partners/sub-recipients?

Appendix G – Biographical Sketches and Position Descriptions

Include position descriptions and biographical sketches for all project staff as supporting documentation to the application. The formatting requirements outlined in Appendix B are not applicable for these documents.

Biographical Sketch

Existing curricula vitae of project staff members may be used if they are updated and contain all items of information requested below. You may add any information items listed below to complete existing documents. For development of new curricula vitae include items below in the most suitable format:

1. Name of staff member
2. Educational background: school(s), location, dates attended, degrees earned (specify year), major field of study
3. Professional experience
4. Recent relevant publications

Position Description

1. Title of position
2. Description of duties and responsibilities
3. Qualifications for position
4. Supervisory relationships
5. Skills and knowledge required
6. Amount of travel and any other special conditions or requirements
7. Salary range
8. Hours per day or week

Appendix H – Addressing Behavioral Health Disparities

SAMHSA expects recipient to submit a Behavioral Disparity Impact Statement (DIS) within 60 days of receiving the award.

SAMHSA’s Behavioral Health Disparity Impact Statement (DIS) is a data-driven, quality improvement approach to advance equity for all, and to identify racial, ethnic, sexual and gender minority, and rural populations at highest risk for experiencing behavioral health disparities as part of their projects. The purpose of the DIS is for recipient to identify and address health disparities¹³ and to develop and implement an action plan with a disparity reduction quality improvement process to close the identified gap(s). The aim is to achieve targeted behavioral health equity¹⁴ for disparate populations and improve systems.

SAMHSA provides a DIS Worksheet that award recipient is expected to use to respond to this special condition of award.

The main components of the DIS are:

- Identify and describe the scope of the problem (i.e., behavioral health disparity) related to the program and the population(s) of focus that experience disparate access, use, and outcomes. Identify data sources that will be used to inform the DIS (this should be in alignment with the information provided in your application). Complete a table that includes this information at the individual/client, organizational or systemic level as it relates to the data collection requirements: NOMS, IPP, or both, in relation to access, use, and outcomes.

¹³ Healthy People 2030 defines a health disparity as a “particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.”

¹⁴ Behavioral health equity is the right to access high quality and affordable health care services and supports for all populations regardless of the individual’s race, age, ethnicity, gender (including gender identity), disability, socioeconomic status, sexual orientation, or geographical location. Advancing behavioral health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with quality services, this involves addressing social determinants of health, such as employment and housing stability, insurance status, proximity to services, and culturally responsive care – all of which have an impact on behavioral health outcomes.

- Identify Social Determinant of Health (SDOH) domain(s) that your organization will work to address and improve for the identified population(s) of focus using the NOFO. Visit [Healthy People 2030](#) for more information on the five (5) domains. Using the Behavioral Health Implementation Guide, identify Culturally and Linguistically Appropriate Services (CLAS) standards that your organization plans to meet, expand, or improve through this funding opportunity. Review the [Behavioral Health Implementation Guide](#) for full explanations of the overarching themes and 15 CLAS Standards with behavioral health related samples, strategies, and examples.
- Develop and implement a disparity reducing quality improvement action plan to address the behavioral health disparity(ies) experienced by underserved population differences based on the GPRA data on access, use, and outcomes of activities. The plan should include realistic goals and SMART objectives (see [Appendix E](#)), the activities that will be implemented to address disparities, the intended impact, timeline, measurement, and evaluation. Ensure documentation of the processes, progress, and outcomes on how the identified behavioral health disparity(ies) have improved.

Recipient is expected to provide, at a minimum, an annual update on the DIS (e.g., what worked, what did not work, what modifications were made) as part of the programmatic progress reports per the NOFO.

Examples of a DIS are available on the SAMHSA website at <http://www.samhsa.gov/grants/grants-management/disparity-impact-statement>

DIS Related Terminology and Resources

Definition of Health Disparities

Healthy People 2030 defines a health disparity as a “particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.”

Social Determinants of Health (SDOH)

[SDOH](#) are the conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOH can be grouped into 5 domains:

- Economic Stability
- Education Access and Quality

- Health Care Access and Quality
- Neighborhood and Built Environment
- Social and Community Context

For more information about SDOH Z codes and how SDOH are being used to narrow the health disparities gaps, see <https://www.cms.gov/files/document/zcodes-infographic.pdf>; <https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf>; and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207437/pdf/18-095.pdf>

Definition of Equity

Equity is the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Addressing issues of equity should include an understanding of intersectionality and how multiple forms of discrimination impact individuals' lived experiences. Individuals and communities often belong to more than one group that has been historically underserved, marginalized, or adversely affected by persistent poverty and inequality. Individuals at the nexus of multiple identities often experience unique forms of discrimination or systemic disadvantages, including in their access to needed services.

Definition of Health Equity

Health equity is the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities. Behavioral health equity is the right to access quality health care for all populations regardless of the individual's race, ethnicity, gender, socioeconomic status, sexual orientation, or geographical location. This includes access to prevention, treatment, and recovery services for mental and substance use disorders.

Underserved populations

SAMHSA applicants are routinely asked to define the population they intend to serve given the focus of a particular program (e.g., adults with opioid use disorders at risk of overdose; adults with serious mental illness [SMI]; adolescents engaged in underage drinking; populations at risk for contracting HIV/AIDS, etc.). Within these populations of focus are *underserved populations* that may have unequal access to, use of, or outcomes from provided services. These disparities may be the result of differences in race, ethnicity, language, culture, and/or socioeconomic factors specific to that

underserved population. For instance, Latino adults with opioid use disorder may be at heightened risk for overdoses due to lack of in-language prevention campaigns and treatment; African Americans with an SMI may more likely to terminate treatment prematurely due to lack of providers with whom they can develop a therapeutic relationship; Native American youth may have an increased incidence of underage drinking due to coping patterns related to historical trauma; and African American women may be at greater risk for contracting HIV/AIDS due to lack of access to education on risky sexual behaviors in urban low-income communities, etc. While these factors might not be pervasive among the general population served by a recipient, they may be predominant among underserved populations or groups vulnerable to disparities. It is imperative that recipient understand who is being served, who is underserved, and who is not being served within their community in order to provide outreach and care that will yield positive outcomes, per the focus of the award. For organizations to attend to the potentially disparate impact of their award efforts, recipient is asked to address access, use and outcomes, disaggregated by underserved populations. Underserved populations can be defined by the following factors:

- By race
- By ethnicity
- By gender identity (including transgender populations)
- By sexual orientation (including lesbian, gay and bisexual populations)

Access refers to which populations/underserved populations are being served/reached by the program. Use refers to what interventions/services are received by the various populations. Outcomes refers to the outcome measures stipulated by the award and examined across underserved populations.

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

The ability to address the quality of care provided to underserved populations served within SAMHSA's programs is enhanced by programmatic alignment with the federal National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards).

The CLAS Standards are comprised of 15 Standards that provide a blueprint for health and health care organizations to implement culturally and linguistically appropriate, respectful, and responsive services that will advance health equity, improve quality, and help eliminate health care disparities.

The CLAS Standards are grouped into a Principal Standard and three themes focused on

- 1) Governance and Leadership.
- 2) Communication and Language Assistance.
- 3) Engagement, Continuous Improvement and Accountability.

Widely embraced by States and health care systems, the National CLAS Standards are more recently being promoted in behavioral health care, which includes a Behavioral Health CLAS Implementation Guide at https://www.minorityhealth.hhs.gov/Assets/PDF/clas%20standards%20doc_v06.28.21.pdf. You can learn more about the CLAS mandates, guidelines, and recommendations at: <https://thinkculturalhealth.hhs.gov/clas>.

Guidelines for behavioral health implementation of the CLAS Standards can be found at <https://thinkculturalhealth.hhs.gov/clas>. This document addresses the importance of improving access to behavioral health care, promoting quality behavioral health programs and practice, and ultimately reducing persistent disparities in mental health and substance use prevention, treatment, and recovery for underserved, minority populations and communities.

Appendix I – Standard Funding Restrictions

HHS codified the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*, 45 CFR Part 75. In Subpart E, cost principles are described and allowable/unallowable expenditures for HHS recipients are delineated. 45 CFR Part 75 is available at <https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-75>. Unless superseded by program statute or regulation, follow the cost principles in 45 CFR Part 75 and the standard funding restrictions below.

Guidelines for recipients on financial management requirements are available at <https://www.samhsa.gov/grants/grants-management/policies-regulations/financial-management-requirements>.

SAMHSA funds may not be used to:

- Purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 CFR. 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase, or distribution of marijuana).
- Purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances.
- Pay for promotional items including, but not limited to, clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags. (See 45 CFR 75.421(e)(3))
- Pay for the purchase or construction of any building or structure to house any part of the program. Minor alterations and renovations (A&R) may be authorized for up to 25% of a given budget period or \$150,000 (whichever is less) for existing facilities, if necessary and appropriate to the project. Minor A&R may not include a structural change (e.g., to the foundation, roof, floor, or exterior or loadbearing walls of a facility, or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change the function and purpose of the facility. All minor A&R must be approved by SAMHSA.
- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.
- Pay for housing other than recovery housing which includes application fees and security deposits
- Make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services (See 42 U.S.C. § 1320a-7b).

Note: A recipient or treatment or prevention provider may provide up to \$30 non-cash incentive to individuals to participate in required data collection follow-up. This amount may be paid for participation in each required follow-up interview. For programs including contingency management as a component of the treatment program, each individual contingency must be \$15 or less in value and clients may not receive contingencies totaling more than \$75 per budget period.

- Meals are generally unallowable unless they are an integral part of a conference award or specifically stated as an allowable expense in the NOFO (See <https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-food/index.html>)
- Purchase firearms.
- General Provisions under Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act Public Law 117-328, Consolidated Appropriations Act, 2023, Division H, Title V, Section 526, notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. Provided, that such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with state and local law.
- **Salary Limitation:** The Consolidated Appropriations Act, 2023 (Public Law 117-328), Division H, Title II, Section 202, provides a salary rate limitation. The law limits the salary amount that may be awarded and charged to SAMHSA awards and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II, which is **\$212,100**. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to your organization. This salary limitation does not apply to consultants but does apply to subrecipients under a SAMHSA award or cooperative agreement . Note that these or other salary limitations will apply in the following fiscal years, as required by law.

Appendix J – Intergovernmental Review (E.O. 12372) Requirements

States with SPOCs

All SAMHSA programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. Certain jurisdictions have elected to participate in the EO process and have established State Single Points of Contact (SPOCs). Information on the SPOC for participating states can be found at: <https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf>

This requirement does not apply to American Indian/Alaska Native tribes or tribal organizations. If your state participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the state's review process. For proposed projects serving more than one state, you are advised to contact the SPOC of each affiliated state.

The SPOC should send any state review process recommendations to the following address within 60 days of the application deadline:

Director, Division of Grants Management
Office of Financial Resources,
ATTN: SPOC – Funding Announcement No. SM-23-019
Substance Abuse and Mental Health Services Administration,
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

States without SPOCs

If your state does not have a SPOC and you are a community-based, non-governmental service provider, you must submit a Public Health System Impact Statement (PHSIS)¹⁵ to the head(s) of appropriate state and local health agencies in the area(s) to be affected no later than the application deadline. The PHSIS is intended to keep state and local health officials informed of proposed health services applications submitted by community-based, non-governmental organizations within their jurisdictions. If you are

¹⁵ Approved by OMB under control no. 0920-0428; Public reporting burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the first page of SF-424 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).

a state or local government or American Indian/Alaska Native tribe or tribal organization, you are not subject to these requirements.

The PHSIS consists of the following information:

- A copy of the first page of the application (SF-424); and
- A summary of the project, no longer than one page in length that provides: 1) a description of the population to be served; 2) a summary of the services to be provided; and 3) a description of the coordination planned with appropriate state or local health agencies.

For SAMHSA awards, the appropriate state agencies are the Single State Agencies (SSAs) for substance abuse and mental health. A listing of the SSAs for substance abuse and the SSAs for mental health can be found on SAMHSA's website at <http://www.samhsa.gov/grants/applying/forms-resources>. If the proposed project falls within the jurisdiction of more than one state, you should notify all representative SSAs.

Review Section IV of the NOFO carefully to determine if you must include an attachment with a copy of a letter transmitting the PHSIS to the SSA. The letter must notify the state that, if it wishes to comment on the proposal, its comments should be sent no later than 60 days after the application deadline to the following address:

Director of Grants Management
Office of Financial Resources,
ATTN: SSA – Funding Announcement No. SM-23-019.
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

In addition, applicants may request that the SSA send them a copy of any state comments. The applicant must notify the SSA within 30 days of receipt of an award.

Appendix K – Administrative and National Policy

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website.

HHS Grants Policy Statement (GPS)

If your application is funded, you are subject to the requirements of the HHS Grants Policy Statement (GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at <http://www.samhsa.gov/grants/grants-management/policies-regulations/hhs-grants-policy-statement>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the NoA).

HHS Award Regulations

If your application is funded, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR 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. For more information see the SAMHSA website at <http://www.samhsa.gov/grants/grants-management/policies-regulations/requirements-principles>.

Additional Terms and Conditions

Depending on the nature of the specific funding opportunity and/or your proposed project as identified during review, SAMHSA may negotiate additional terms and conditions with you prior to award. These may include, for example:

- actions required to be in compliance with confidentiality and participant protection/human subjects requirements.
- requirements relating to additional data collection and reporting.
- requirements relating to participation in a cross-site evaluation.
- requirements to address problems identified in review of the application or the budget and narrative justification.

Performance Goals and Objectives

If your application is funded, you will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the award and the amount of any continuation award. In addition, you must relate financial data and accomplishments to the performance goals and objectives of the award. Failure to meet stated goals and objectives may result in suspension or termination (see [2 CFR](#)

[200.202](#), [2 CFR 200.301](#) and [2 CFR 200.329](#)) of the award, or in reduction or withholding of continuation awards.

Termination of Federal Award

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at [2 CFR § 200.340](#) - Termination apply to all federal awards effective August 13, 2020.

Accessibility Provisions for All Award Application Packages and Funding Opportunity Announcements

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

You will administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. You will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws require taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by 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>.

- 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 providing program access, reasonable

modifications, and to provide effective communication, see <https://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 project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated antidiscrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

Acknowledgement of Federal Funding

As required by HHS appropriations acts, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations, and other documents, such as tool-kits, resource guides, websites, and presentations describing the projects or programs funded in whole or in part with HHS federal funds. The recipient must clearly state: 1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and 2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

Supplement Not Supplant

Funds may be used to supplement existing activities. Award funds may not be used to supplant current funding of existing activities. “Supplant” is defined as replacing funding of a recipient’s existing program with funds from a federal award (2 CFR Part 200, Appendix XI).

Mandatory Disclosures

A term may be added to the NoA which states: Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the HHS awarding agency, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Sub-recipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to SAMHSA at the following address:

SAMHSA
Attention: Office of Financial Advisory Services
5600 Fishers Lane
Rockville, MD 20857

You may also submit a complaint via the [OIG Hotline online form](https://oig.hhs.gov/fraud/report-fraud/) (see <https://oig.hhs.gov/fraud/report-fraud/>), by phone (1-800-447-8477), or by mail to the following address:

U.S. Dept. of Health and Human Services
Office of the Inspector General
ATTN: OIG Hotline Operations
P.O. Box 23489
Washington, DC 20026

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance; including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321)."

System for Award Management (SAM) Reporting

A term may be added to the NoA that states: "In accordance with the regulatory requirements provided at 45 CFR 75.113, 2 CFR 25, and Appendix XII to 45 CFR Part 75, recipients that have currently active federal awards and procurement contracts with cumulative total value greater than \$10,000,000, must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a federal award that reached final disposition within the most recent five-year period. The recipient also must make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system [currently Responsibility/Qualification in SAM.gov (R/Q)]. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75."

Drug-Free Workplace

A term may be added to the NoA that states: "You as the recipient must comply with drug-free workplace requirements in Subpart B of part 382, which adopts the Government-wide implementation (2 CFR part 182) of section 5152-5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701-707)."

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, 20 USC 6081 et seq., the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Standards for Financial Management

Recipients and subrecipients are required to meet the standards and requirements for financial management systems set forth in 45 CFR part 75 Subpart D. The financial systems must enable the recipient and subrecipient to maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. The system must also enable the recipient and subrecipient to compare actual expenditures or outlays with the approved budget for the award. SAMHSA funds must retain their award/subaward-specific identity and may not be commingled with non-federal funds or other federal funds. "Commingling funds" typically means depositing or recording funds in a general account without the ability to identify each specific source of funds with related expenditures. Common mistakes related to comingling are outlined below:

- **Commingling of Cost Centers:** Every business activity constitutes a cost center. Examples of cost centers include: a federal award, a state award, a private award, matching costs for a specific award, a self-funded project, fundraising activities, membership activities, lines of business, unallowable costs, indirect costs, etc. Recipients and subrecipients must establish a unique account(s) in the accounting system to capture and accumulate expenditures of each cost center, apart from other cost centers.
- **Commingling of Cost Categories:** Recipients and subrecipients must avoid budget fluctuations that violate programmatic restrictions. They must also avoid applying indirect cost rates to prohibited cost categories, such as equipment, participant support costs and subcontracts/subawards in excess of \$25,000. As a result, recipients must establish unique object codes in the accounting system to capture and 59 accumulate costs by budget category (i.e., salaries, fringe benefits, consultants, travel, participant support costs, subcontracts, etc.).
- **Commingling of Time Worked and Not Worked:** Recipients and subrecipients may not directly charge an award for employees' time not spent working on the award. Therefore, Paid Time Off (PTO), such as vacation, holiday, sick and other paid leave, is not recoverable directly from awards, but rather must be allocated to all awards, projects, and cost centers over an entire cost accounting period through either an indirect cost or fringe benefit rate.
- **Unsupported Labor Costs:** To support charges for direct and indirect salaries and wages, recipients and subrecipients maintaining hourly timesheets must ensure that timesheets encompass all hours worked and not worked on a daily basis. The timesheet should identify the: (a) award, project or cost center being worked on; (b) number of hours worked on each; (c) description of work performed; and (d) Paid Time Off (PTO) hours. The total hours recorded each day should coincide with an individual's employment status in accordance with established policy (i.e., fulltime employees work 8 hours each day, etc.).
- **Inconsistent Treatment of Costs:** Recipients and subrecipients must treat costs consistently across all federal and non-federal awards, projects, and cost centers. For example, recipients and subrecipients may not direct-charge federal awards for costs typically considered indirect in nature, unless done consistently.

Examples of indirect costs include administrative salaries, office rent, accounting fees, utilities, etc. Additionally, in most cases, the cost to develop an accounting system adequate to justify direct charging of the aforementioned items outweighs the benefits. As a result, use of an indirect cost rate is the most effective mechanism to recover these costs and not violate federal financial requirements of consistency, allocability and allowability. If typical indirect cost categories are included in the budget as direct costs, it is SAMHSA's understanding that the recipient or subrecipient has developed a cost accounting system that can withstand audit scrutiny and therefore the system must be adequate to justify the direct charges and to avoid an unfair allocation of these costs to the federal government. All costs are subject to subsequent agency review and/or audit scrutiny in accordance with awards' terms and conditions.

Trafficking in Persons

Awards issued by SAMHSA are subject to the requirements of [2 CFR part 175](#) and [22 USC 7104\(g\)](#). For the full text of the award term, go to <http://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions>.

NOTE: The signature of the AOR on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

Publications

Recipients are required to notify the Government Project Officer (GPO) of any materials based on the SAMHSA-funded project that are accepted for publication. In addition, SAMHSA requests that recipients:

- Provide the GPO with advance copies of publications.
- Include acknowledgment of the SAMHSA program as the source of funding for the project.
- Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S. Department of Health and Human Services and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance use treatment/substance use prevention/mental health services community.

Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

As described in [2 CFR 200.216](#), recipients and subrecipients are prohibited to obligate

or spend award funds (to include direct and indirect expenditures as well as cost share and program) to:

- (1) Procure or obtain,
- (2) Extend or renew a contract to procure or obtain; or
- (3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
 - i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
 - ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
 - iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

Appendix L – Budget and Justification

All applications must have a detailed budget justification and narrative that explains the federal and the non-federal expenditures broken out by the object class cost categories listed on SF-424A – Section B (Budget Category) for non-construction awards.

- The detailed budget must match the costs identified on the SF-424A and the total costs on the SF-424.
- The Budget Narrative and justification must be consistent with and support the Project Narrative.
- The Budget Narrative and justification must be concrete and specific. It must provide a justification for the basis of each proposed cost in the budget and how that cost was calculated. Examples to consider when justifying the basis of your estimates can be ongoing activities, market rates, quotations received from vendors, or historical records. The proposed costs must be reasonable, allowable, allocable, and necessary for the supported activity.
- NOFOs invite applications for periods of performance of one to up to five years. Generally, awards, on a competitive basis, will be for a one-year budget period but the period of performance may be up to five years. Submission and SAMHSA approval of the progress report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the multi-year period of performance is subject to availability of funds and satisfactory progress of the recipient. Progress will be evaluated by submission of data on required performance measures, satisfactory achievement of identified goals and objectives, providing services to the projected number of individuals specified in the application, and satisfactory resolution of barriers and challenges that arise in the implementation of the project.
- Refer to the program specific Funding Restrictions/Limitations and the Standard Funding Restrictions in the NOFO, as well as to 45 CFR Part 75 (<https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75>), for applicable administrative requirements and cost principles.

SAMHSA Budget Template

To expedite review of your application, it is highly recommended you use the following PDF budget template to complete the Detailed Budget and Narrative Justification for submission with your application:

- The budget template can be found on the [SAMHSA Forms and Resources webpage](#) – scroll down to “**SAMHSA Budget Template**” section. You **must**

download the budget template PDF to your computer first before opening it directly in Adobe Acrobat or Acrobat Reader (not your internet browser):

1. Right-click the link "**SAMHSA Budget Template (PDF)**"
2. Select "save link as" and save to a location on your computer
3. Go to the saved location and open the "SAMHSA Budget Template (PDF)" using Adobe Acrobat or Acrobat Reader.

Guidance

The following documents provide guidance on using the budget template:

- [Key Features of the Budget Template](#)
- [Budget Template Users Guide](#)
- [Budget Review Checklist](#) – use this checklist to review your detailed budget and narrative justification before submission to SAMHSA.

Note: For SAMHSA to view all of your budget data, you must convert the PDF to a non-editable format by **PRINTING TO PDF** before submission.

Completing the SF-424A (see Section IV)

Budget Cost Categories

Personnel Costs: Explain personnel costs by listing each staff member who will be working directly on the award by name (if possible), position title, percentage level of effort or proposed hours and annual salary. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or **\$212,100**. An individual's base salary, per se, is NOT constrained by the statutory provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to SAMHSA awards and cooperative agreements. The salary limitation does not apply to consultants but does apply to all subawards and subcontracts.

Note: If an organization is selected for an award and chooses to move forward with hiring an individual for a Key Personnel position before receiving SAMHSA's formal approval, this will be done at the organization's own risk. If SAMHSA's review of the Key Personnel request results in the proposed individual not being approved or deemed not qualified for the position, the expectation is that the organization must submit a qualified candidate to be placed in the Key Personnel position. SAMHSA will not be liable for any costs incurred or pay for salaries of a Key Personnel that is not approved or deemed not qualified for the program.

Fringe Benefits: Fringe benefits typically include items, such as health insurance, taxes, unemployment insurance, life insurance, retirement plans, tuition reimbursement and

paid absences. Fringe benefits are recoverable in accordance with an organization's federally approved indirect cost rate agreement, if applicable, or the organization's accounting practices, provided those practices are consistent with federal cost principles and result in a fair and equitable allocation of fringe benefits.

Travel: List travel costs according to local and long-distance travel. For local travel, outline the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel. The budget should also reflect the travel expenses (e.g., airfare, lodging, parking, per diem, etc.) for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s) if possible, describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals for whom funds are requested.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of \$5,000 or more and a useful life of one or more years). For example, large items of medical equipment.

Supplies: Include the programmatic items necessary to implement the proposed project (e.g., examination gloves, etc.). Conversely, general office supplies (e.g., paper, pencils, etc.) should be recovered through a federally-approved indirect cost rate or de minimis rate.

Per 45 CFR § 75.321, property will be classified as supplies if the acquisition cost is under \$5,000. Note that items such as laptops, tablets, and desktop computers are classified as a supply if the value is under the \$5,000 equipment threshold.

Vendor Contracts/Subawards & Subcontracts/Consortiums/Consultants: Provide a clear explanation as to the purpose, the basis for how costs were estimated, and the specific deliverables. You are responsible for ensuring that your organization has adequate procurement and merit review systems with fully developed written procedures for awarding and monitoring vendor contracts and subawards/subcontracts, respectively. Recipients must notify potential subrecipients to register in SAM and provide the recipient with their UEI number (see 2 CFR part 25). For consultant services, list the total costs for all consultant services. In the budget narrative, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

Note: To assist with classifying costs and relationships, note that vendor contracts are for the purpose of obtaining goods and services (i.e., examination gloves provided by a medical supply company). Conversely, subawards/subcontracts are for the purpose of carrying out a portion of a federal award (i.e., a health care clinic providing substance use treatment services directly to patients). Your organization must ensure proper classification of costs and relationships. For subrecipient relationships, your

organization must ensure written subaward/subcontract agreements are in place. These written agreements must require that subrecipients comply with the same terms and conditions as the prime recipient, as applicable (i.e., financial management requirements, audit requirements, etc.) In other words, the requirements imposed on the prime recipient must “flow down” to subrecipients. Written agreements should also describe the scope of work, deliverables, etc.

Other: Include all costs that do not fit into any other category and provide an explanation of each cost in this category (e.g., provider licenses, dedicated space rental, etc.).

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For some institutions, the term “facilities and administration” (F&A) is used to denote indirect costs.

Applicants may request full indirect costs, subject to statutory and regulatory limitations.

Applicants may request full indirect costs, subject to statutory and regulatory limitations, and submission of an approved Negotiated Indirect Cost Rate Agreement (NICRA) established by the cognizant Federal agency (typically the agency that provides the most funds). If indirect costs are claimed, a copy of the NICRA must be submitted with the application. If unable to obtain a NICRA from the cognizant agency at the time of application, the applicant may elect to recover indirect costs using a de minimis rate as explained below. Otherwise, the applicant may only be reimbursed for allowable direct costs. Violation of cost accounting principles is not permitted when re-budgeting or charging costs to awards. Rather, costs must be consistently charged as either indirect or direct costs.

Applicants may elect a 10% de minimis indirect cost rate, subject to statutory and regulatory limitations.

Applicants who cannot obtain a NICRA from their cognizant Federal agency at the time of application may elect a 10% de minimis rate, subject to statutory and regulatory limitations.

The 10% *de minimis* rate may be used indefinitely and should be applied to Modified Total Direct Costs (MTDC). MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award.) MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000. Violation of cost accounting principles is not permitted when charging costs to awards. Rather, costs must be consistently charged as either direct or indirect costs. Additionally, once elected, the 10% *de minimis* rate must be applied to all existing awards. If the cognizant agency

issues a NICRA subsequent to the award, the negotiated rate may *not* be retroactively applied.

Waived Indirect Costs – An applicant may elect *not* to request recovery of indirect costs. If so, the applicant should write *None Requested* in the same space allotted for Item J of the budget sheet.