Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

FY 2022 Harm Reduction Program Grant

(Short Title: Harm Reduction)

(Modified Announcement)

Notice of Funding Opportunity (NOFO) No. SP-22-001

Assistance Listing Number No.: 93.243

Key Dates:

Application Deadline	Applications are due by February 7, 2022.
Intergovernmental Review (E.O. 12372)	Applicants must comply with E.O. 12372 if their state(s) participate(s). Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after 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 administrative 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 fiscal year (FY) 2022 Harm Reduction Program Grants (Short Title: Harm Reduction). The purpose of the program is to support community-based overdose prevention programs, syringe services programs, and other harm reduction services. Funding will be used to enhance overdose and other types of prevention activities to help control the spread of infectious diseases and the consequences of such diseases for individuals with, or at risk of developing substance use disorders (SUD), support distribution of FDA-approved overdose reversal medication to individuals at risk of overdose, build connections for individuals at risk for, or with, a SUD to overdose education, counseling, and health education, refer individuals to treatment for infectious diseases, such as HIV, sexually transmitted infections (STIs), and viral hepatitis, and encourage such individuals to take steps to reduce the negative personal and public health impacts of substance use or misuse. This will include supporting capacity development to strengthen harm reduction programs as part of the continuum of care. Recipients will also establish processes, protocols, and mechanisms for referral to appropriate treatment and recovery support services. Grantees will also provide overdose prevention education to their target populations regarding the consumption of substances including but not limited to opioids and their synthetic analogs. Funds may also be used to help address the stigma often associated with risky behaviors and participation in harm reduction activities.

Funding Opportunity Title:	Harm Reduction Program Grant (Short Title: Harm Reduction)
Funding Opportunity Number:	SP-22-001
Due Date for Applications:	February 7, 2022
Estimated Total Available Funding:	Up to \$9,750,000 per year or \$29,250,000 over 3 years
Estimated Number of Awards:	25 awards
Estimated Award Amount:	Up to \$400,000 per award per year
Cost Sharing/Match Required:	No
Anticipated Project Start Date:	May 30, 2022
Anticipated Award Date:	May 15, 2022
Length of Project Period:	Up to 3 years

Eligible Applicants:	Eligible applicants are States; local, Tribal, and territorial governments; Tribal organizations; non-profit community-based organizations; and primary and behavioral health organizations [See Section III.1] for complete eligibility information.]
Authorizing Statute	Section 516(a) of the Public Health Services (PHS) Act, as amended and Section 2706 of the American Rescue Plan (ARP) Act.

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

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

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.

Applicants also must register with the System for Award Management (SAM) and Grants.gov (See <u>Appendix A – Application and Submission Requirements</u> for all registration requirements.)

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 Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is accepting applications for fiscal year (FY) 2022 Harm Reduction Program Grants (Short Title: Harm Reduction). The purpose of the program is to support community-based overdose prevention programs, syringe services programs, and other harm reduction services. Funding will be used to enhance overdose and other types of prevention activities to help control the spread of infectious diseases and the consequences of such diseases for individuals with, or at risk of developing substance use disorders (SUD), support distribution of FDA-approved overdose reversal medication to individuals at risk of overdose, build connections for individuals at risk for, or with, a SUD to overdose education, counseling, and health education, refer individuals to treatment for infectious diseases such as HIV, sexually transmitted infections (STIs), and viral hepatitis, and encourage such individuals to take

steps to reduce the negative personal and public health impacts of substance use or misuse. This will include supporting capacity development to strengthen harm reduction programs as part of the continuum of care. Recipients will also establish processes, protocols, and mechanisms for referral to appropriate treatment and recovery support services. Grantees will also provide overdose prevention education to their target populations regarding the consumption of substances including but not limited to opioids and their synthetic analogs. Funds may also be used to help address the stigma often associated with substance use and participation in harm reduction activities.

The priority populations for this program are underserved communities that are greatly impacted by SUD. Underserved communities are defined under section 2 of <u>Executive Order 13985</u>. Grant recipients will focus activities on "meeting people where they're at" within the context of harm reduction through integrating trauma-informed care and facilitating the use of peer support workers in programming.

The Harm Reduction grant program is authorized under Section 516(a) of the PHS Act, as amended and Section 2706 of the ARP Act of 2021.

2. KEY PERSONNEL

Key personnel are staff members who must be part of the project regardless of whether they receive a salary or compensation from the project. These staff members must make a substantial contribution to the execution of the project.

The Key Personnel for this program are the Project Director and the Peer Support Worker. These position(s) require prior approval by SAMHSA after a review of staff credentials and job descriptions.

3. REQUIRED ACTIVITIES

In Section C.1 of the Project Narrative, applicants must indicate the total number of unduplicated individuals you expect to serve each year of the grant and over the total project period. You are expected to achieve the numbers that are proposed.

Project implementation is expected to begin by the <u>fourth month</u> of the grant.

These are the activities that every grant project must implement. Required activities must be reflected in the Project Narrative in Section V of this NOFO.

Grant funds must be used primarily to support the following required harm reduction activities:

 Assess organizational readiness and create a strategic action plan based upon identified strengths, gaps (including those related to social determinants of health), and opportunities for capacity development required to implement an evidence-based harm reduction program at the service delivery and organizational levels. This strategic action plan should be developed by the midpoint of Year 1 and will be supported by the Harm Reduction TA Center (https://www.cdc.gov/harmreductionta/index.html).

- Develop a sustainability plan to ensure that harm reduction program elements are continued after the grant period ends. This could include collaboration with community partners to share resources or a cost sharing element.
- Develop policies and procedures to implement evidence-based trauma-informed practices throughout each level of the organizational structure.
- Distribute FDA-approved overdose reversal medication and deliver overdose prevention education to target populations regarding the consumption of substances including but not limited to opioids and their synthetic analogs.
- Establish processes, protocols, mechanisms for referral to treatment and recovery support services, referral to treatment for infectious diseases such as HIV, STIs, and viral hepatitis.
- Assemble a harm reduction advisory council that meets regularly to guide program activities and project implementation. Group members should include people who use drugs (PWUD), individuals in recovery, harm reduction service providers and other key community members such as public safety officers, mental health providers and treatment providers.
- Designate staff (e.g., Program Coordinator and/or Program Evaluator) to provide program design, implementation, and evaluation to meet grant program and reporting requirements.
- Purchase equipment and supplies to enhance harm reduction efforts, such as:
 - Harm reduction vending machine(s), including stock for machines;
 - Infectious diseases testing kits (HIV, HBV, HCV, etc.);
 - Medication lock boxes:
 - FDA-approved overdose reversal medication (as well as higher dosages now approved by FDA);
 - Safe sex kits, including PrEP resources and condoms;
 - Safe smoking kits/supplies;
 - Screening for infectious diseases (HIV, sexually transmitted infections, viral hepatitis):
 - Sharps disposal and medication disposal kits;
 - Substance test kits, including test strips for fentanyl and other synthetic drugs;
 - Syringes to prevent and control the spread of infectious diseases;
 - Vaccination services (hepatitis A, hepatitis B vaccination); and
 - Wound care management supplies.

Harm reduction programs that use federal funding must adhere to federal, state, and local laws, regulations, and other requirements related to such programs or services.

The Harm Reduction grant program is authorized under Section 2706 of the American Rescue Plan Act of 2021 which is not subject to the same syringe funding restrictions as other federal grants.

4. ALLOWABLE ACTIVITIES

Grant funds may be used, but are not required, for the following allowable activities:

- Hire and train staff to effectively deliver comprehensive harm reduction services, including but not limited to mobile outreach, motivational interviewing techniques and trauma-informed approaches to break the cycle of trauma.
- Implement a communication campaign focused on reducing stigma related to harm reduction.
- Provide support services for individuals receiving harm reduction services, including but not limited to screening, referral, linkage to care, and warm handoffs to partner services focused on substance use and/or cessation, infectious disease, mental health, primary care, housing, and other psychosocial needs.
- Utilize innovative approaches (i.e., <u>overdose fatality review team</u> and low threshold buprenorphine induction) in harm reduction programs.
- Provide public education on any state "Good Samaritan" laws related to harm reduction.

5. USING EVIDENCE-BASED PRACTICES

SAMHSA's services grants are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. An evidence-based practice (EBP) refers to approaches to prevention, treatment, or recovery that are validated by some form of documented research evidence. Both researchers and practitioners recognize that EBPs are essential to improving the effectiveness of treatment and prevention services. While SAMHSA realizes that EBPs have not been developed for all populations and/or service settings, application reviewers will closely examine proposed interventions for evidence base and appropriateness for the population of focus.

To identify evidence-informed and culturally appropriate mental illness and substance use prevention and treatment practices that can be implemented in your project, applicants are encouraged to visit SAMHSA's Evidence-Based Practice Resource Center (www.samhsa.gov/ebp-resource-center), SAMHSA's National Network to Eliminate Disparities in Behavioral Health (NNED) (https://nned.net/), HHS's Overdose Prevention Strategy (https://nned.net/), HHS's Overdose Evidence-Based Strategies for Preventing Opioid Overdose (https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf), and NIH's Stigma and Discrimination Research Toolkit

(https://www.nimh.nih.gov/about/organization/dar/stigma-and-discrimination-research-toolkit).

CDC's Syringe Services Program Technical Package of Effective Strategies and Approaches for Planning, Design, and Implementation. https://www.cdc.gov/ssp/docs/SSP-Technical-Package.pdf

6. DATA COLLECTION/PERFORMANCE MEASUREMENT AND PROJECT PERFORMANCE ASSESSMENT

Data Collection/Performance Measurement

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. You must document your plan for data collection and reporting in your Project Narrative in response to Section D: Data Collection and Performance Measurement in Section V of this NOFO.

Recipients will be required to report on the following indicators on a quarterly basis via SAMHSA's Performance Accountability and Reporting System (SPARS):

- Number of individual **referrals** to support services.
- Number of individual **linkages** to support services. For the purposes of this indicator, "linkages" are defined as the number of **engagements** with any support service. Each linkage should be counted (i.e., one individual participant engaged with five individual support services should reflect five linkages).
- List and quantity of harm reduction materials purchased with grant funds including, but not limited to:
 - Harm reduction vending machine(s), including stock for machines;
 - o Infectious diseases testing kits (HIV, HBV, HCV, etc.);
 - Medication lock boxes;
 - FDA-approved overdose reversal medication(as well as higher dosages now approved by FDA);
 - o Safe sex kits, including PrEP resources and condoms;
 - Safe smoking kits/supplies;
 - Screening for infectious diseases (HIV, sexually transmitted infections, viral hepatitis);
 - Sharps disposal and medication disposal kits;
 - Substance test kits, including test strips for fentanyl and other synthetic drugs;
 - Syringes to prevent and control the spread of infectious diseases;
 - o Vaccination services (hepatitis A, hepatitis B vaccination); and
 - Wound care management supplies.
- Evidence-based interventions or promising practices implemented at the community level.

 Organizational policy changes developed and/or implemented because of this grant, including efforts made towards stigma reduction.

This information will be gathered using a uniform data collection tool provided by SAMHSA. Recipients are required to submit data via SPARS and access will be provided upon award. An example of the required data collection tool can be found here https://www.samhsa.gov/grants/gpra-measurement-tools/csap-gpra. The frequency of data reporting will be quarterly.

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

An evaluation may be required to build the evidence base for this program. Grant recipients may be required to participate fully in all aspects of the evaluation. This may include collection of additional data and participation of sub-recipients. If applicable, details on the evaluation, including type of evaluation and questions, will be provided.

Project Performance Assessment

Recipients 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 grant project. Recipients are also required to report on their progress addressing the goals and objectives identified in your Project Narrative.

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 also be used to determine whether your project is having/will have the intended impact on behavioral health disparities.

Note: See <u>Appendix E</u> and <u>Appendix F</u> of this NOFO for more information on responding to this section.

7. OTHER EXPECTATIONS

Behavioral Health Disparities

If your application is funded, you will be expected to develop a behavioral health disparity impact statement no later than 60 days after your award. (See <u>Appendix H</u> – Addressing Behavioral Health Disparities).

Behavioral health equity refers to 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. Advancing 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 (SDOH), such as employment and housing stability, insurance status, proximity to services, culturally responsive care – all of which have an impact on behavioral health outcomes.

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."

Tribal Behavioral Health Agenda

SAMHSA, working with tribes, the Indian Health Service, and National Indian Health Board developed the first collaborative National Tribal Behavioral Health Agenda (TBHA). Tribal applicants are encouraged to briefly cite the applicable TBHA foundational element(s), priority(ies), and strategies that are addressed by their grant application. The TBHA can be accessed at http://nihb.org/docs/12052016/FINAL%20TBHA%2012-4-16.pdf.

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).

Reimbursements for the Provision of Services

Recipients must utilize third party reimbursements and other revenue realized from the provision of services to the extent possible and use SAMHSA grant funds only for services to individuals who are not covered by public or commercial health insurance programs, individuals for whom coverage has been formally determined to be unaffordable, or for services that are not sufficiently covered by an individual's health insurance plan. Recipients are also expected to facilitate the health insurance application and enrollment process for eligible uninsured clients. Recipients should also consider other systems from which a potential service recipient may be eligible for services (for example, the Veterans Health Administration or senior services), if appropriate for and desired by that individual to meet his/her needs. In addition, recipients are required to implement policies and procedures that ensure other sources of funding are utilized first when available for that individual.

Behavioral Health for Military Service Members and Veterans

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

8. GRANTEE MEETINGS

All grantee meetings will be held virtually, and grantees are expected to fully participate in these meetings. If SAMHSA elects to hold an in-person meeting, budget revisions will be permitted.

II. FEDERAL AWARD INFORMATION

Funding Mechanism: Grant

Anticipated Total Available Funding: Up to \$9,750,000 per year or \$29,250,000 over

3 years

Estimated Number of Awards: 25 awards

Estimated Award Amount: Up to \$400,000 per year per award

Length of Project Period: Up to 3 years

Proposed budgets cannot exceed \$400,000 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

The eligibility for this grant program is defined in Section 2706 of the American Rescue Plan Act of 2021. Eligible applicants are:

- States:
- Local, tribal, and territorial governments;
- Tribal organizations;
- Non-profit community-based organizations; and
- Primary and behavioral health organizations.

It is recommended that you review information on eligibility in Appendix C.

All non-profit entities must submit documentation of non-profit status in Attachment 8.

Tribal organization means the recognized body of any Al/AN tribe; any legally established organization of Al/ANs which is controlled, sanctioned, or chartered by such governing body, or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Al/ANs in all phases of its activities. Consortia of tribes or tribal organizations are eligible to apply, but each participating entity must indicate its approval. A single tribe in the consortium must be the legal applicant, the recipient of the award, and the entity legally responsible for satisfying the grant requirements.

2. COST SHARING and MATCHING REQUIREMENTS

Cost sharing/match is not required in this program.

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 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 <u>Appendix A - 2.2</u> 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 - 4.2 Waiver of Electronic Submission of this NOFO.

- **SF-424** Fill out all Sections of the SF-424.
 - o In **Line #4** (i.e., Applicant Identifier), input the Commons Username of the PD/PI.
 - o In **Line #17** input the following information: (Proposed Project Date: a. Start Date: 5/30/2022; b. End Date: 5/29/2025).
- **SF-424A BUDGET INFORMATION FORM** Fill out all Sections of the SF-424A using 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 <u>first year</u> 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 <u>first year</u> of your project only.
 - Section C As cost sharing/match is not required for this program, leave this section blank
 - **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 and Year 3). For example, if you are requesting funds for three years in total, enter the requested budget amount for each budget period in columns b and c (i.e., 2 out years). - (b) First column is the budget for the second budget period; (c) Second column is the budget for the third budget period. Use Line 16 for federal funds and Line 17 for non-federal funds.

See <u>Appendix B</u>, to review common errors in completing the SF-424 and the SF-424A. These errors will prevent your application from being successfully submitted.

A link to a sample budget form and justification is provided in Appendix L - Sample Budget and Justification of this document. It is highly recommended that you use this sample budget format. This will expedite review of your application.

PROJECT NARRATIVE – (Maximum 10 pages total)

The Project Narrative describes your project. It consists of Sections A through E. (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 <u>Section V.1</u> – 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 <u>Appendix A</u> – 2.2 Required Application Components.)

ATTACHMENTS 1 THROUGH 10

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: Letter of Commitment
 Letters of Commitment from any organization(s) participating in the proposed project. (Do not include any letters of support. Reviewers will not consider them.)
- Attachment 2: Data Collection Instruments/Interview Protocols If you are using standardized data collection instruments/interview protocols, you do <u>not</u> 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

Forms to be submitted 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; and (3) informed consent for the exchange (releasing or requesting) of confidential information.

Attachment 4: Project Timeline

This attachment is scored by reviewers. Maximum of 2 pages. See instructions in B.3 in Section V of this NOFO.

- Attachment 5: Biographical Sketches and Position Descriptions
 See Appendix G 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 Intergovernmental Review (E.O. 12372) Requirements, of this NOFO; 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 Nonprofit Status
 Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit 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 clearly establishes nonprofit 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 nonprofit affiliate.
- Attachment 9: Form SMA 170 Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations You are required to complete Form SMA 170 if your project is offering substance use prevention or treatment services. This form is posted on SAMHSA's website at http://www.samhsa.gov/grants/applying/forms-resources.
- Attachment 10 Population of Focus Certification

You must include a written statement certifying that you are an applicant with more than 50% of your total population(s) of focus, either individually or collectively, belonging to underserved communities that are greatly impacted by SUD. Underserved communities are defined under section 2 of Executive Order 13985. Include the percent of each underserved community within the geographic catchment area for your project. If not applying as an applicant with more than 50% of your population of focus belonging to underserved communities that are greatly impacted by SUD, you do not need to submit this attachment.

3. UNIQUE ENTITY IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT (SAM)

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 period of 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 **February 7, 2022**. 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 <u>Appendix A</u> for information on how to submit the application.

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

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.

Applicants must also register with the System for Award Management (SAM) and Grants.gov (see Appendix A for all registration requirements).

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 total grant award for the budget period may be used for:
 - Administrative costs; and
 - Data collection, performance measurement, and performance assessment, including incentives for participating in the required data collection follow-up.
- State recipients are required to use a minimum of 80 percent of their funds to support subrecipient communities (the priority populations for this program are underserved communities that are greatly impacted by SUD) that demonstrate a need for harm reduction programming in their selected prevention priority(ies).
- Recipients must use funding to supplement and not supplant existing prevention activities in their organization. The rule against supplanting SAMHSA grant funds applies to activities funded by HRSA, CDC, CMS and other federal programs.

Be sure to identify the expenses above in your proposed budget.

SAMHSA recipients must also comply with SAMHSA's standard funding restrictions, which are included in Appendix1 - Standard Funding Restrictions.

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

All SAMHSA grant 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

In awarding Harm Reduction grants, SAMHSA will prioritize funding for programs which address the needs of underserved communities that are greatly impacted by SUD. Underserved communities are defined under section 2 of Executive Order 13985. Communities disproportionately impacted by SUD, based on SAMHSA and/or CDC's most recent available estimates of people who use drugs, which is publicly available at: https://www.datafiles.samhsa.gov/, https://www.cdc.gov/drugoverdose/index.html.

1. EVALUATION CRITERIA

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

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

- The Project Narrative (Sections A-E) together may be no longer than **10 pages**.
- You must use the four sections/headings listed below in developing your Project Narrative. You <u>must</u> 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: Population(s) of Focus and Statement of Need (20 points – approximately 2 ½ pages)

- 1. Identify and describe your population(s) of focus and the geographic catchment area where services will be delivered using relevant data (e.g., official data from federal, state or counties; organizational current and/or historical service data, etc.). Provide a demographic profile of the population(s) of focus in the catchment area in terms of race, ethnicity, federally recognized tribe (if applicable), language, sex, gender identity, sexual orientation, age, housing status, and other socioeconomic indicators. Identify the source(s) of the data which support this section.
- 2. Describe how and why your organization has identified a need for harm reduction services in your selected population(s) of focus, and how the project will reach your population(s) of focus. When documenting the extent of need, describe existing service gaps, health disparities and incidence of poor health indicators influenced by social determinants of health. Use relevant socioeconomic, psychosocial, and public health data to further demonstrate the need for harm reduction services in the population(s) of focus (e.g., healthcare utilization, current incidence and prevalence rates, overdose data, etc.). Identify each source of data.

SECTION B: Bonus Points for Providing Services to Priority Populations (10 points – approximately ½ page)

An additional 10 points will be given to applicants with more than 50 percent of their total population(s) of focus in underserved communities that are greatly impacted by SUD. Underserved communities are defined under section 2 of <u>Executive Order 13985</u>.

1. Specify the percentage of your population(s) of focus that are in underserved communities as defined under section 2 of Executive Order 13985. If more than 50 percent of your population(s), of focus will not be in underserved communities indicate so in your response.

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

1. Describe the goals and measurable objectives (see Appendix E) of the proposed project and align them with the Statement of Need described in A.2. Provide the following table:

Projected Number of Unduplicated Individuals to be Reached with Grant Funds				
	Year 1	Year 2	Year 3	Total
Number of unduplicated individual service encounters.				
Projected Number of Referrals and Linkages to be Supported by Gi Funds			by Grant	
Number of referrals to support services.*				
Number of linkages to support services.**				

^{*}For the purposes of this indicator, "referrals" are defined by the number of referrals made for clients to support services. A referral does not indicate linkage for this number. Each referral should be counted (i.e. one individual participant referred to five different services should reflect 5 referrals.

Describe how you will implement the Required Activities in <u>Section I.3</u> including your organizational harm reduction service delivery model and addressing how your project will utilize culturally informed strategies and evidence-based interventions.

^{**}For the purposes of this indicator, "linkages" are defined as the number of engagements with any support service. Each linkage should be counted (i.e. one individual participant linked to five different services should reflect 5 linkages.

3. Provide a table depicting a realistic timeline for the entire three years of the project period showing dates, required activities, and responsible staff. These key activities must include the required activities outlined in Section I.3
[NOTE: Be sure to show that the applicant organization has necessary resources in place so that the project can be implemented, and service delivery can begin as soon as possible and no later than four months after grant award. The timeline cannot be more than two pages and should be submitted in Attachment 4.] The recommendation of pages for this section does not include the timeline.

SECTION D: Staff and Organizational Experience (20 points – approximately 2 page)

- 1. Discuss organizational background, purpose, and goals. Include the organization's annual operating budget, total number of staff, and services provided.
- 2. Describe the historical and current capacity of the applicant organization to implement harm reduction services to the population(s) of focus, including previously related project successes and outcomes. Explain how your organization measures their capacity and success. If applicable, identify other organization(s) that will partner with the proposed project. Describe their experience providing harm reduction services to the population(s) of focus, and their specific roles and responsibilities for this project. Letters of Commitment from each partner organization must be included in **Attachment 1**. Please indicate if there are no intended partnerships with other organizations.
- 3. Provide a complete list of staff positions for the project, including the Key Personnel (Project Director and Peer Support Worker). For each staff: list their title, project role, level of effort, qualifications, program/service experience, and familiarity with the culture and language of the population(s) of focus.

Section E: Data Collection and Performance Measurement (15 points – approximately 1 page)

1. Provide specific information about how the applicant organization will collect the required data for this program and how such data will be utilized to manage, monitor, and enhance the program. Describe the organizations experience evaluating public health programs and which staff will be engaged in data collection and quarterly reporting for this project.

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, as well as a description of existing resources and other support you expect to receive for the proposed project. Other support is defined as funds or resources, whether federal, 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.

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 budget must reflect the required activities and funding limitations/restrictions specified in Section IV.3. Specifically identify the items associated with these costs in your budget.

3. REVIEW AND SELECTION PROCESS

SAMHSA applications are peer-reviewed according to the evaluation criteria listed above.

Decisions to fund a grant are based on:

- The strengths and weaknesses of the application as identified by peer reviewers. The results of the peer review are of an advisory nature. The program office and approving official make the final determination for funding;
- SAMHSA will review and prioritize funding for programs which address the needs of underserved communities, as defined under section 2 of <u>Executive</u> <u>Order 13985</u>, that are greatly impacted by SUD.
- When the individual award is over \$250,000, approval by the CSAP National Advisory Council;
- Availability of funds;
- Equitable distribution of awards in terms of geography (including urban, rural and remote settings) and balance among populations of focus and program size;
- Submission of any required documentation that must be submitted prior to making an award; and

 SAMHSA is required to review and consider any information about your organization that is in the Federal Award Performance and Integrity Information System (FAPIIS). 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 Federal Awardee Performance and Integrity Information System (FAPIIS)]. You may review and comment on any information about your organization that that federal awarding agency previously entered. SAMHSA will consider your comments, in addition to other information in FAPIIS 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 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 NoA will be emailed to the following: 1) the BO's email address identified in the Authorized Representative section email field on page 4 of the SF-424; and 2) the email associated with the Commons account for the Project Director (section 8 Item f on page 2 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 grant 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 - <a href="https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-noa/s

<u>conditions</u>. See <u>Appendix K</u> for specific information about administrative and national policy requirements.

4. REPORTING REQUIREMENTS

Quantitative and qualitative data described in <u>Section I.6</u> will be reported quarterly in SPARS. In addition, you will be required to submit:

- An organizational readiness assessment at the midpoint of Year 1 (i.e. 6 months post award);
- A strategic action plan to address gaps and build on strengths identified through the organizational readiness assessment at the endpoint of Year 1; and
- A quarterly progress report.

Quarterly progress reports must discuss project progress, including successes and barriers encountered, and efforts to overcome these barriers. Refer to <u>Section VI.1</u> for any program specific information on the frequency of reporting and any additional requirements.

A final performance report must be submitted within 120 days after the end of the final budget period. The final performance report must be cumulative and report on all grant activities during the entire project period. Refer to Section VI.3 for any program specific information on the frequency of reporting and any additional requirements.

Grants Management:

Successful applicants must also comply with the following standard grants management reporting requirements at https://www.samhsa.gov/grants/grants-management/reporting-requirements, unless otherwise noted in the NOFO or Notice of Award (NoA).

VII. AGENCY CONTACTS

For program related and eligibility questions contact:

Cara Alexander
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services Administration
(240) 276-0578
DTPHarmReduction@samhsa.hhs.gov

For fiscal/budget related 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:

Sherresa Bailey-Jones
Office of Financial Resources, Division of Grant Review
Substance Abuse and Mental Health Services Administration
(240) 276-1359
sherresa.bailey@samhsa.hhs.gov

Appendix A – Application and Submission Requirements

1. GET REGISTERED

You are required to complete four (4) registration processes:

- 1.1) Dun & Bradstreet Data Universal Numbering System (to obtain a DUNS number);
- 1.2) System for Award Management (SAM);
- 1.3) Grants.gov; and
- 1.4) eRA Commons.

If this is your first time submitting an application, you must complete all four registration processes. Please take note of the timing for these registrations.

If you have already completed registrations for DUNS, SAM, and Grants.gov, you need to ensure that your accounts are still active, and then register in **eRA Commons** (see 1.4).

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 grant 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 Dun & Bradstreet Data Universal Numbering System (DUNS) Registration

If your organization is not compliant when SAMHSA is ready to make an award, SAMHSA may determine that your organization is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

SAMHSA applicants are required to obtain a valid DUNS Number, also known as the Unique Entity Identifier, and provide that number in the application. Obtaining a DUNS number is easy and there is no charge. (The DUNS Number will be phased out by April 2022. Organizations will be assigned a new 12-character identifier.) The organization must maintain active and up-to-date SAM and DUNS registrations for SAMHSA to make an award. The DUNS number needs to be valid and verifiable in order to register for eRA Commons.

To obtain a DUNS number, access the Dun and Bradstreet website at: http://www.dnb.com or call 1-866-705-5711. To expedite the process, let Dun and

Bradstreet know that you are a public/private nonprofit organization getting ready to submit a federal grant application. The DUNS number you use on your application must be registered and active in the System for Award Management (SAM).

1.2 System for Award Management (SAM) Registration

You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information during the period of 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 so 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 prior to 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 recipients 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 a new account requires.

1.3 Grants.gov Registration

<u>Grants.gov</u> is an online portal for submitting federal grant applications. It requires a one-time registration to submit applications. While Grants.gov registration is a one-time only registration process, it consists of multiple sub-registration processes (i.e., DUNS number and SAM registrations) before you can submit your application. [Note: eRA Commons registration is separate but can be done concurrently. See 1.4.]. 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 DUNS 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.

1.4 eRA Commons Registration

eRA Commons is an online data platform managed by NIH that allows applicants, award recipients, and federal staff to securely share, manage, and process grant-related information. It is strongly recommended that you start the eRA Commons registration process at least six (6) weeks prior to 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 BO named in the Authorized Representative section field on page 4 of the SF-424 and the Project Director details entered in the Applicant Information item f on page 2 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 in order to have access to electronic submission and retrieval of application/grant 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 online <u>Institution</u> <u>Registration Form</u>. Instructions on how to complete the online Institution Registration Form is provided on the eRA Commons Online Registration Page.

[Note: You must have a valid and verifiable DUNS 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 a Commons User ID for the Signing Official account ('SO') role. The representative will receive a separate email pertaining to this SO account containing a temporary password to be used for the first-time log in. The representative will need to log into 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 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 in order 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 2 of the SF-424 assigning that person the 'PI' role in 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).

You can find additional information about the eRA Commons registration process at https://era.nih.gov/reg accounts/register commons.cfm.

2. WRITE AND COMPLETE 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. Call the Division of Grant Review at 240-276-1199 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
Federal Assistance) Form SAMHSA grants. The names and contact informati Director (PD) and Business Offici for SAMHSA applications, and ar the SF-424 form. • The PD must have an eF account: the PD's Comm must be entered in field 4 Identifier; and the PD's i number and email addres in Section 8. APPLICAN item f. Name and conta person to be contacted		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. • 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	Grants.gov/forms
		 involving this application. The BO name, title, email address and phone number must be entered in the Authorized Representative section fields on page four of the SF 424. The organization mailing address is required in section 8. APPLICANT INFORMATION item d. Address. 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 	
2	SF-424 A (Budget Information – Non- Construction Programs) Form	the Signing Official/Business Official (SO/BO). 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.	Grants.gov/forms
3	Project/Performance Site Location(s) Form	The purpose of this form is to collect location information on the site(s) where work funded under this grant announcement will be performed.	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.	

#	Standard Application Components	Description	Where to Find Document
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 grantor 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 "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. You must sign and submit this form, if applicable.	Grants.gov/forms
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	Description	Where to Find
	Documents		Document

1	HHS 690 Form	Every grant applicant must have a completed HHS 690 form (PDF 291 KB) on file with the Department of Health and Human Services.	SAMHSA Website
2	Charitable Choice Form SMA 170 (Attachment 9)	See Section IV-1 of the NOFO to determine if you are required to submit Charitable Choice Form SMA 170. If you are, you can upload this form to Grants.gov when you submit your application.	SAMHSA Website
3	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.
4	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 7)	See the NOFO or requirements related to confidentiality, participant protection, and the protection of human subject's regulations.	NOFO: See Appendix D
5	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 SF424 form set, submit electronically through Grants.gov to SAMHSA and other participating agencies, and track grant 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: <u>eRA Modules, User Guides, and Documentation</u> | 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 240-276-1199.

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:

- By e-mail: 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 emails 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. 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 <u>Warning</u> notification after the application is submitted, you are <u>not required to resubmit</u> 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 <u>Error</u> notification after the applications is submitted, you <u>must</u> <u>correct and resubmit the application</u>. 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 <u>one business day after the official due date at:</u> <u>dgr.applications@samhsa.hhs.gov</u> 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 <u>if</u> 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 <u>Project Title is identical to the Project Title in the originally submitted</u> <u>application</u> (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 grant 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.
- 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 <u>must be 'error free'</u> to be processed through the eRA Commons. There may be additional validations which will result in Warnings but these <u>will not</u> 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
#1: Applicant Identifier (Item 4 on the SF-424):	
The PD/PI Credentials must be provided	The Commons Username must be provided in the Applicant Identifier field for the PD/PI.
Username provided must be a valid Commons account	The Commons Username provided in the Applicant Identifier is not a recognized Commons account.
Username must be affiliated with the organization submitting the application and or have the PI role	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.
#2. The DUNS number provided must include valid characters (9 or 13 numbers with or without dashes)	The DUNS number provided has invalid characters (other than 9 or 13 numbers) after stripping of dashes
#3. The documentation (forms) required for the NOFO must be submitted	The format of the application does not match the format of the NOFO. Contact the eRA Service Desk for assistance.
#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.	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.
#5. The application cannot exceed 1.2GB.	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.
#6. The correct Notice of Funding Opportunity (NOFO) number must be provided	The Funding Opportunity Announcement number does not exist.
#7. All documents and attachments must be submitted in PDF format.	"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 g uidelines.htm."</attachment>
#8. All attachments must comply with the following formatting requirements:	

eRA Validations	eRA Error Messages
PDF attachments cannot be empty (0 bytes).	The {attachment} attachment was empty. PDF attachments cannot be empty, password protected or encrypted.
All PDF attachments cannot have Meta data missing, cannot be encrypted, password protected or secured documents.	The <attachment> attachment contained formatting or features not currently supported by NIH: <condition returned="">.</condition></attachment>
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.]	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/pdfguidelines.htm</file>
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.	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.</attachment>
#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.	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.
#10. Congressional district code of applicant (after truncating) must be valid. (SF-424, item 16 a and b)	Congressional district < Congressional District> is invalid. To locate your district, visit http://www.house.gov/

Budget Errors			
eRA Validations	eRA Error Messages		
SF424-A: Section A – Budget Summary 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	Ensure that the sum of Grant Program Function or Activity (a) elements entered equals the total amounts in the Total field		
SF424-A: Section B – Budget Categories The Total in Section B (Column 5 - Row k) must equal the Total in Section A – Budget Summary: (Row 5, Column g).	Ensure that the TOTALS Total (row k, column 5) equals the Budget Summary Totals in section A, row 5 column g.		
SF424-A: Section D – Forecasted Cash Needs The Federal Total for the 1st Year (Line 13) must equal the Total in Section A (Row 5, Column g)	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.		
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)	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.		
The Total for 1st Year TOTAL in Section D must equal the Totals Total (Column 5, Row G) in Section A	Ensure that the Forecasted Cash Needs: 15. TOTAL equals to SECTION A – Budget Summary: 5.Totals Total (g).		
SF424-A: Section E – Budget Estimates of Federal Funds Needed for Balance of The Project			
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.	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.		

Appendix C – General Eligibility Information

Determining whether you are eligible to apply for and receive a SAMHSA grant 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 grant.

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 grant. 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

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 (Al/AN) tribes

Nonprofit Organizations

Nonprofits having a 501(c)(3) status with the Internal Revenue Service (IRS), other than institutions of higher education

Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education

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

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 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.

1. Protect Clients 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.

2. Fair Selection of Participants

- Explain how you will recruit and select participants.
- 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.

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 have included funding for incentives in your budget, you must address this item. (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.)
- 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 that they may receive services even if they chose to not participate in or complete the data collection component of the project.

4. Data Collection

- Identify from whom you will collect data (e.g., participants, 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 instrument(s)/protocol(s)).

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: Recipients must maintain the confidentiality of alcohol and drug abuse client records according to the provisions of <u>Title 42 of the Code of Federal</u> <u>Regulations</u>, <u>Part 2</u>, <u>Subpart B</u>.

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; and
- 3. informed consent for the exchange (releasing or requesting) of confidential information.
- The sample forms must be included in **Attachment 3**, "**Sample Consent Forms**", of your application. If needed, give English translations.
- 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.

7. Risk/Benefit Discussion

 Discuss why the risks you have identified in Element 1. Protect Clients and Staff from Potential Risks are reasonable compared to the 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 <u>measurable</u> 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

<u>Definition</u> – 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 abuse and HIV/AIDS prevention capacity of the local school district	This goal could be improved by specifying an expected program effect in reducing a health problem	Increase the capacity of the local school district to reduce high-risk behaviors of students that may contribute to substance abuse 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

<u>Definition</u> – 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
Teachers will be trained on the selected evidence-based substance abuse prevention curriculum.	The objective is not SMART because it is not specific, measurable, or time-bound. It can be made SMART by specifically indicating who is responsible for training the teachers, how many will be trained, who they are, and by when the trainings will be conducted.	By June 1, 2020, LEA supervisory staff will have trained 75% of health education teachers in the local school district on the selected, evidence-based substance abuse prevention curriculum.
90% of youth will participate in classes on assertive communication skills.	This objective is not SMART because it is not specific or time-bound. It can be made SMART by indicating who will conduct the activity, by when, and who will participate in the lessons on assertive communication skills.	By the end of the 2020 school year, district health educators will have conducted classes on assertive communication skills for 90% of youth in the middle school receiving the substance abuse and HIV prevention curriculum.
Train individuals in the community on the prevention of prescription drug/opioid overdoserelated deaths.	This objective is not SMART as it is not <i>specific, 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.	By the end of year two of the project, the Health Department will have trained 75% of EMS staff in the County Government on the selected curriculum addressing the prevention of prescription drug/opioid overdose-related deaths.

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:

- What electronic data collection software that will be used.?
- How often data will be collected?
- The organizational processes that will be implemented to ensure the accurate and timely collection and input of data.
- The staff that will be responsible for collecting and recording the data.
- The data source/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.
- How will the data be kept secure.
- If applicable, how will the data collection procedures ensure that confidentiality is protected, and that informed consent is obtained. and
- If applicable, how data will be collected from partners, sub-awardees.

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.

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

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

Data Management

Points to consider:

- How data will be protected, including information about who will have access to data.
- How will data be stored.
- The staff member who will be responsible for tracking the performance measures and measurable objectives.
- Who will be responsible for conducting the data analysis, including the role of the Evaluator?
- What data analysis methods will be used.
- Who will be responsible for completing the reports?
- How will the data be reported to staff, stakeholders, SAMHSA, Advisory Board, and other relevant project partners.

Data Monitoring

Points to consider:

- How frequently performance data will be reviewed.
- How you will use this data to monitor and evaluate activities and processes and to assess the progress that has been made achieving the goals and objectives?
- Who will be responsible for monitoring the data?

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?
- The staff members who will be responsible for overseeing these processes.
- How you will implement any needed changes in 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-awardees?

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 recipients to submit a Behavioral Disparity Impact Statement (DIS) within 60 days of receiving the grant award. The DIS is a data-driven, quality improvement effort to ensure under-resourced populations are addressed in the grant. The DIS is built on the required GPRA data such that no additional data collection is required. It is expected that the DIS will be no more than two pages in length.

The DIS consists of three components:

- (1) Number of individuals to be served during the grant period and identify underresourced population(s) (i.e., racial, ethnic, sexual, and gender minority groups) vulnerable to behavioral health disparities.
- (2) A quality improvement plan to address under-resourced population differences based on the GPRA data on access, use and outcomes of service activities.
- (3) Methods for the development of policies and procedures to ensure adherence to the Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care.

As part of SAMHSA's Disparity Impact Statement requirements, include the number of unduplicated individuals to be served by under-resourced populations in the grant implementation area provided in a table that covers the entire grant period. The under-resourced population(s) should be identified in a narrative that includes a description of the population and a rationale for how the determination was made. Include demographic data and an environmental scan of the population(s) of focus. For data about your population(s) of focus, refer to

https://www.census.gov/about/partners/cic.html. Indicate what the disparity(ies) is and how your services and activities will be monitored and implemented to close the gap(s). In addition, describe how you will evaluate and disseminate the findings to your stakeholders.

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

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)

Social determinants of health (<u>SDOH</u>) 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.ncbi.nlm.nih.gov/pmc/articles/PMC6207437/pdf/18-ndbl.pdf; and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207437/pdf/18-ndbl.pdf;

In Section 1, the National Outcome Measures (NOMS) tool collects employment, education, perception of care, housing stability and social connectedness information.

Definition of Health Equity

Health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. 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.

Under-resourced populations

SAMHSA grant applicants are routinely asked to define the population they intend to serve given the focus of a particular grant 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 *under-resourced 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 under-resourced 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 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 under-resourced populations or groups vulnerable to disparities. It is imperative that recipients understand who is being served, who is under-resourced, 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 grant. For organizations to attend to the potentially disparate impact of their grant efforts, recipients are asked to address access, use and outcomes, disaggregated by under-resourced populations. Under-resourced populations can be defined by the following factors:

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

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

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

The ability to address the quality of care provided to under-resourced populations served within SAMHSA's grant 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.p df. You can learn more about the CLAS mandates, guidelines, and recommendations at: http://www.ThinkCulturalHealth.hhs.gov.

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 under-resourced, 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 and 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.

You may also reference the SAMHSA site for grantee guidelines on financial management requirements at https://www.samhsa.gov/grants/grants-management/policies-regulations/financial-management-requirements.

SAMHSA grant funds may not be used to:

- SAMHSA grant funds may not be used to promote the use of, purchase, prescribe, or provide marijuana or treatment using marijuana. See, General Provisions under Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, Public Law 116-260, Consolidated Appropriations Act, 2021, Division H, Title V, Section 509 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana).
- 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. Applicants may request up to \$150,000 or 25% of the budget for a budget period (whatever is less) for alterations and renovations (A & R) of 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. You may request up to \$150,000 for minor A&R to accommodate the equipment to make the space suitable for use for the proposed project.
- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.
- 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 grant 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).
- Salary Limitation: The Consolidated Appropriations Act, 2021 (Public Law 116-260), 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 grants 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 \$199,300. 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 also applies to subrecipients under a SAMHSA grant 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 grant 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

You do not need to do this if you are an American Indian/Alaska Native tribe or tribal organization. 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. SP-22-001
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)¹ 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

¹ 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).

local health officials informed of proposed health services grant applications submitted by community-based, non-governmental organizations within their jurisdictions. If you are a <u>state or local government or American Indian/Alaska Native tribe or tribal organization</u>, 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 grants, 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. SP-22-001.
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 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.

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 Grant 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 grant award. These may include, for example:

- actions required to be in compliance with confidentiality and participant protection/human subjects requirements;
- o requirements relating to additional data collection and reporting;
- o requirements relating to participation in a cross-site evaluation;
- requirements to address problems identified in review of the application; or revised 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 grant and the amount of any continuation award. Failure to meet stated goals and objectives may result in suspension or termination (see 45 CFR.75.372) of the grant award, or in reduction or withholding of continuation awards.

Termination of Federal Award

If a decision is made to terminate your award, the following provisions of <u>45 CFR 75.372</u> will be applicable:

- You will receive a notice of termination:
- If the termination is related to your failure to comply with Federal statutes, regulations, or terms and conditions of the award, the notification will state:
 - The termination decision has been reported to the Federal Awardee Performance and Integrity Information System (FAPIIS) accessible through the System for Award Management (SAM);
 - The information will be available in FAPIIS for a period of five years from the date of the termination and then archived;
 - Federal awarding agencies that consider making a Federal award to your organization during that five-year period are required to consider that information in judging whether your organization is qualified to receive the Federal award, when the Federal share of the award is expected to exceed the simplified acquisition threshold over the period of performance;
 - Your organization may comment on any information in FAPIIS for future consideration by Federal awarding agencies. You may submit comments to the awardee integrity and performance portal accessible through SAM (CPARS);
 - Federal awarding agencies will consider your comments when determining whether your organization is qualified for a future Federal award; and
 - SAMHSA will provide information about the termination to the Federal website established to fulfill the requirements of the Federal Funding Accountability and Transparency Act (FFATA) and update and notify any other relevant governmentwide systems or entities of any indications of poor performance.

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The

HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.html and https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.hhs.gov/fact-sheet-guidance/index.html and https://www.lep.gov. For further guidance on providing culturally and linguistically appropriate services, recipients should review the Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at: https://www.minorityhealth.hhs.gov/minority-mental-health/clas/?utm medium=email&utm source=govdelivery
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment. See https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html; https://www.ocrsm.umd.edu/files/Sexual-Harassment-Fact-Sheet.pdf.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

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

Grant funds may be used to supplement existing activities. Grant 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 grant (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, with a copy to the HHS Office of Inspector General (OIG), 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) and the HHS OIG, 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

AND by email to grantdisclosures@oig.hhs.gov or by mail to the following address:

Office of Counsel to the Inspector General Office of the Inspector General U.S. Dept. of Health and Human Services Grant Self-Disclosures 330 Independence Avenue SW Cohen Building Room 5527 Washington, DC 20201

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 grants 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). 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 (or Subpart C, if the recipient is an individual) 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 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 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 to compare actual expenditures or outlays with the approved budget for the award.

SAMHSA funds must retain their award-specific identity – they may not be commingled with state 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 for any expenditure.]. 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 grant, a state grant, a private grant, matching costs for a specific grant, a self-funded project, fundraising activities, membership activities, lines of business, unallowable costs, indirect costs, etc. Recipients 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 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 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 may not directly
 charge a grant for employees' time not spent working on the grant. Therefore,
 Paid Time Off (PTO), such as vacation, holiday, sick and other paid leave, is not
 recoverable directly from grants, but rather must be allocated to all grants,
 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 maintaining hourly timesheets must ensure that timesheets encompass all hours worked and not worked on a daily basis. The timesheet should identify the: (a) grant, 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., full-time employees work 8 hours each day, etc.).
- Inconsistent Treatment of Costs. Recipients must treat costs consistently across all federal and non-federal grants, projects, and cost centers. For example, recipients may not direct-charge federal grants for costs typically considered indirect in nature, unless done consistently. Examples of indirect costs include administrative salaries, 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. See the appendix titled "Sample Budget and Justification," for additional indirect cost guidance.

Trafficking in Persons

Awards issued by SAMHSA are subject to the requirements of <u>2 CFR part 175</u> and <u>22 USC 7104(g)</u>. 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) and SAMHSA's Publications Clearance Officer (240-276-2130) of any materials based on the SAMHSA-funded grant project that are accepted for publication. In addition, SAMHSA requests that recipients:

- Provide the GPO and SAMHSA Publications Clearance Officer with advance copies of publications
- Include acknowledgment of the SAMHSA grant 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 abuse treatment/substance abuse prevention/mental health services community.

Appendix L – Sample 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 budget narrative must match the costs identified on the SF-424A form 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, satisfactory progress of the recipient, and a determination that continued funding would be in the best interest of the Federal Government. 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:

- To locate the budget template <u>Click here SAMHSA Forms and Resources</u> 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
- <u>Budget Review Checklist</u> 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.

Sample Budgets

The following PDFs are samples of Detailed Budgets and Narrative Justification:

- Sample Budget NON-MATCH (PDF | 697 KB)
- Sample Budget MATCH (PDF | 729 KB)

Completing the SF-424A

Complete Sections A – F of the SF-424A Budget Information – Non-Construction Programs form included with the application package for each year of the period of performance. The budget period is for one year. However, you must submit one-year budgets for each of the subsequent budget periods within the requested period of performance at the time of application.

In **Section A** use rows 1–4 to provide the budget amounts for the first four years of the project. Enter the amounts in the "New or Revised Budget" column- not the "Estimated Unobligated Funds" column. In Section B 6. Object Class Categories of the SF-424A, provide the object class category breakdown (i.e., line item budget) for each year of the period of performance specified in Section A.

In **Section B**, use column (1) to provide category amounts for year one and use columns (2) through (4), if applicable, for subsequent budget years. If applicable for year five, submit a copy of Section B of the SF-424A as an Attachment (specific attachment number will be listed in the NOFO - not counted in the page limit).

Section C – Non-Federal Resources: complete only if Section III. 2. Cost Sharing/Matching of the NOFO indicates that cost sharing/matching is required. Lines 8–11 correspond to the first four years of the project. If applicable for year five, submit a copy of Section C of the SF-424A as an Attachment (specific attachment number will be listed in the NOFO).

Section D – Forecasted Cash Needs: If no cost sharing/matching is required, complete only line "13. Federal" in the first column titled "Total for 1st Year." If cost sharing/matching is required, complete all three lines "13. Federal," "14. Non-Federal," and "15. Total (Sum of lines 13 and 14)" in the first column titled "Total for 1st Year."

Section E – Budget Estimates of Federal Funds Needed for Balance of the Project: Complete line 16 of the Future Funding Periods columns for the out years, with (b) First being the 2nd year, (c) Second being the 3rd year, etc.

Section F – Other Budget Information. Complete as appropriate.

Budget Cost Categories

<u>Personnel Costs</u>: Explain personnel costs by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, 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 \$199,300. 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 grants and cooperative agreements.

Note: If an organization is awarded a grant 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 on the grant program.

<u>Fringe Benefits</u>: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project.

<u>Travel</u>: 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.

<u>Equipment</u>: 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.

<u>Supplies</u>: List the items that the project will use to implement the proposed project. Items must be listed separately: office supplies (e.g., paper, pencils).

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.

Contractual/Subawards/Consortium/Consultant: Provide a clear explanation as to the purpose of each contract/subaward, how the costs were estimated, and the specific contract/subaward deliverables. You should provide the basis for your cost estimate for the contract. You are responsible for ensuring that your organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts/subawards. Recipients must notify potential subrecipients that entities receiving subawards must be registered in SAM and provide the recipient with their DUNS 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.

For subawards to entities that will help carry out the work of the award, you should describe how you will monitor their work to ensure the funds are being properly used.

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). In some cases, rent, utilities, and insurance fall under this category if they are not included in an approved indirect cost rate.

<u>Indirect Costs</u>: 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. If your organization does not have an indirect cost rate, you may wish to obtain one through HHS's Cost Allocation Services (CAS) (formerly the Division of Cost Allocation (DCA)). Visit CAS's website to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. If indirect costs are included in the budget, attach a copy of the indirect cost rate agreement.

Any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than \$35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely. If chosen, this methodology once elected must be used consistently for all federal awards until such time as a non-federal entity chooses to negotiate for a rate, which the nonfederal entity may apply to do at any time.