Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

FY 2022 State Opioid Response Grants

(Short Title: SOR)

(Initial Announcement)

Notice of Funding Opportunity (NOFO) No. TI-22-005

Assistance Listing Number: 93.788

Key Dates:

Application Deadline	Applications are due by July 18, 2022.

Table of Contents

EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is accepting applications for the fiscal year (FY) 2022 cohort of the State Opioid Response grant program. The purpose of this program is to address the opioid overdose crisis by providing resources to states and territories for increasing access to FDA-approved medications for the treatment of opioid use disorder (MOUD), and for supporting the continuum of prevention, harm reduction, treatment, and recovery support services for opioid use disorder (OUD) and other concurrent substance use disorders. The SOR program also supports the continuum of care for stimulant misuse and use disorders, including for cocaine and methamphetamine. The SOR program aims to help reduce unmet treatment needs and opioid-related overdose deaths across America.

Funding Opportunity Title:	State Opioid Response
Funding Opportunity Number:	TI-22-005
Due Date for Applications:	July 18, 2022
Estimated Total Available Funding:	$1,439,500,000 (This includes a set-aside for the states hardest hit by the crisis.)
Estimated Number of Awards:	59
Estimated Award Amount:	See Appendix K for estimated award amounts.
Cost Sharing/Match Required:	No
Anticipated Project Start Date:	September 30, 2022
Anticipated Award Date	September 23, 2022
Length of Project Period:	Up to 2 years
Eligible Applicants:	Eligibility is limited to Single State Agencies (SSAs) and territories. Note: Tribes are eligible to apply under a separate announcement. [See Section III-1 for complete eligibility information.]
Authorizing Statute:	SOR grants are authorized under the Consolidated Appropriations Act of 2022, [Public Law 117-103].

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 Appendix A of this NOFO 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 Treatment (CSAT), is accepting applications for the fiscal year (FY) 2022 cohort of the State Opioid Response grant program. The purpose of this program is to address the opioid overdose crisis by providing resources to states and territories for increasing access to FDA-approved medications for the treatment of opioid use disorder (MOUD), and for supporting the continuum of prevention, harm reduction, treatment, and recovery support services for opioid use disorder (OUD) and other concurrent substance use disorders. The SOR program also supports the continuum of care for stimulant misuse and use disorders, including for cocaine and methamphetamine. The SOR program aims to help reduce unmet treatment needs and opioid-related overdose deaths across America.

Recipients and sub-awardees' use of funds for this program requires evidence-based treatments, practices, and interventions for OUD and stimulant use disorders. SAMHSA requires that MOUD be made available to those diagnosed with OUD. MOUD includes methadone, buprenorphine products, including single-entity buprenorphine products, buprenorphine/naloxone tablets, films, buccal preparations, long-acting injectable buprenorphine products, and injectable extended-release naltrexone.

Medically managed withdrawal (the updated term for detoxification) is not the standard of care for OUD, and is associated with a very high relapse rate, while also significantly increasing an individual's risk for opioid overdose and death if opioid use is resumed.[1] Therefore, SAMHSA does not recognize medically managed withdrawal, when done in isolation, as an evidence-based practice for OUD. If medically managed withdrawal services are provided by SOR awardees or sub-awardees, it must be accompanied by the offer and provision of injectable extended-release naltrexone to protect such individuals from opioid overdose in case of return to use and improve treatment outcomes.

In addition to these treatment services, recipients will be required to employ effective prevention, harm reduction, and recovery support services.

The SOR grants are authorized under the Consolidated Appropriations Act, of 2022 [Public Law 117-103].

---

[1] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

2. KEY PERSONNEL

Key personnel are staff members who must be part of the project regardless of whether or not they receive a salary or compensation from the project. These staff members must make a substantial contribution to the execution of the project.

Key Personnel for this program are the Project Director, Project Coordinator, and Data Coordinator at a 1.0 FTE (100 percent level of effort) for each position. Organizations receiving federal funds may not exceed 100 percent level of effort for any program staff member (Key Staff or otherwise) across all federally funded sources. **If during the project period, the recipient changes key personnel, the position requires prior approval by SAMHSA after review of credentials of staff and job descriptions.**

3. REQUIRED ACTIVITIES

Required activities are the activities that every grant project must implement. They must be reflected in the Project Narrative of your application. This is in response to Section V of this NOFO.

Project implementation is expected to begin by the third month of the grant. **Applicants must indicate the total number of unduplicated individuals that will be served each grant year and over the entire project period in Section B of Section V of this NOFO. Of the total number of unduplicated individuals, applicants must specify:**

- **the number of individuals who will receive treatment services***
- **the number of individuals who will receive recovery support services*; and**
- **the number of individuals who will receive prevention services.**

*Note: Of those individuals receiving treatment and recovery support services, applicants must also indicate the total number of individuals who will complete the CSAT Government Performance and Results Act (GPRA) Client Outcome Measures for Discretionary Programs Tool for each grant year; the total receiving treatment and recovery support services will be the applicant's GPRA target in SPARS (see Section B of Section V of this NOFO).

Recipients and sub-awardees must use SAMHSA's grant funds primarily to support direct services. This includes the following activities:

- Develop a needs assessment using statewide epidemiological data. If a needs assessment effort is already in place, work with the local, state, or tribal epidemiological outcomes workgroup to enhance and supplement the current process and update its findings. The needs assessment must be included in **Attachment 8** of your application, and must identify/include:

o The scope of OUD and substance use disorders and overdose mortality in recent years.
o The strengths, unmet service needs, and critical gaps in your service system across diverse racial, ethnic, geographic, and other demographic, groups.
o Areas where opioid and stimulant misuse, substance use disorder, use of emergency medical resources for substance use such as hospitalization, and overdose are the most prevalent.
o The number and location of opioid treatment providers in the state, including Opioid Treatment Programs (OTPs) as well as DATA-waivered office-based opioid treatment providers.
o All existing activities and their funding sources in the state that address opioid and stimulant use prevention, harm reduction (e.g., fentanyl test strip purchase and distribution), treatment, and recovery activities and remaining gaps in these activities.
o A naloxone distribution and saturation plan particularly focused on areas with high rates of overdose mortality. (Note: Naloxone distribution and saturation plan training modules are available at: https://spaces.hightail.com/space/3XsH5zMvCD). Naloxone is an important tool in preventing overdose deaths and many studies have demonstrated the value of naloxone distribution[2] and that increased saturation in communities reduces overdose deaths.[3] This plan must include:

 ▪ The amount of annual naloxone needed to reach saturation in your state's communities and the estimated gap in the current supply;[4]
 ▪ Targeted distribution and communication strategy to get the appropriate type of naloxone into the hands of those most likely to witness an overdose and in the locations where they are most likely to occur;
 ▪ Partnerships with existing public and private efforts external to SOR such as through Medicaid, "buyers' clubs", and recent court settlements;
 ▪ Budget that includes the cost of the naloxone and other operational requirements; and
 ▪ Detailed timeline to implement the plan including procurement requirements.

---

[2] Walley AY, Xuan Z, Hackman HH, Quinn E, Doe-Simkins M, Sorensen-Alawad A, Ruiz S, Ozonoff A. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ. 2013 Jan 30; 346: f174.

[3] Irvine MA, Oller D, Boggis J, Bishop B, Coombs D, Wheeler E, Doe-Simkins M, Walley AY, Marshall BDL, Bratberg J, Green TC. Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study. Lancet Public Health. 2022 Feb 10: S2468-2667(21)00304-2. doi: 10.1016/S2468-2667(21)00304-2. Epub ahead of print. PMID: 35151372.

[4] FRED (A Framework for Reconstructing Epidemiological Dynamics) FRED Web (pitt.edu) provides a helpful resource for some states and counties to plan for their naloxone saturation needs.

- Develop a comprehensive state strategic plan to address the gaps in prevention, harm reduction, treatment, and recovery services related to opioids and stimulants identified in the needs assessment. This plan must address the needs of diverse populations, including underserved populations as defined in Executive Order 13985 (e.g., racial/ethnic minorities and LGBTQI+) and older adults with targeted interventions, when appropriate, as well as strategies and activities that will be incorporated to address to promote behavioral health equity. The plan must also address outreach efforts to engage tribes, tribal organizations, and urban Indian organizations to ensure that strategies are implemented to meet their needs. The strategic plan must be included in **Attachment 9** of your application.

- Implement service delivery models that enable the full spectrum of treatment and recovery support services that facilitate positive treatment outcomes and long-term recovery from opioid and stimulant use disorders. Models for evidence-based treatment include, but are not limited to:

  o Hub and spoke/center of excellence models in which patients with OUD and stimulant use disorder are stabilized in a specialized treatment setting focused on the care and treatment of OUD and stimulants, and associated conditions such as mental illness, physical illness, including infectious diseases, and other substance use disorders, and then transferred to community-based providers once stabilization has occurred.
  o Treatment in federally and state-regulated OTPs.
  o Addiction specialty care programs that either directly provide or support use of MOUD in addition to psychosocial services such as drug counseling, psychoeducation, toxicology testing, individual, group, and/or family therapy, vocational/educational resources, case management, and recovery support services, including community-based services that provide peer supports, address housing needs and issues of families (e.g., reunification of children who may be in foster care while a parent(s) receive treatment); this may include outpatient, intensive outpatient or partial hospital levels of care.
  o Non-specialty settings such as emergency departments, urgent care centers, and in some cases, pharmacies that also support appropriate MOUD and recovery support services.
  o Inpatient/residential programs that provide intensive treatment services to those meeting medical necessity criteria and which offer MOUD provided the care continuum includes a connection to MOUD in the community once individuals are discharged from the inpatient/residential program.
  o Primary care or other clinical practice settings where MOUD is provided and linkages to psychosocial services and recovery support services centered on patient needs related to the provision of comprehensive treatment of OUD.
  o Programs that address the multi-faceted and complex needs of individuals with stimulant use disorder (e.g., polydrug use, psychosis, violence, co-occurring stimulant use and mental disorders, etc.).

- Low threshold MOUD treatment programs that offer services and make minimal requirements of patients, thus removing or reducing barriers to treatment and expanding access to care.
- Innovative telehealth strategies in rural and underserved areas to increase the capacity of communities to support OUD/stimulant use disorder prevention, treatment, and recovery.

- Implement recovery support services, including but not limited to:

    - Peer supports,
    - Recovery coaches,
    - Vocational training,
    - Employment support,
    - Transportation,
    - Childcare,
    - Legal assistance,
    - Recovery Community Organizations,
    - Housing supports (i.e., application fees, deposits, rental assistance, utility deposits, and utility assistance),
    - Dental kits to promote oral health for individuals with OUD enrolled in treatment with buprenorphine (i.e., dental kits are limited to items such as toothpaste, toothbrush, dental floss, non-alcohol containing mouthwash, and educational information related to accessing dental care), and
    - Recovery Housing.

Note: Recovery Housing is one component of the substance use disorders treatment and recovery continuum of care. While recovery residences vary widely in structure, all are centered on peer support and a connection to services that promote long-term recovery. Individuals in recovery should have a meaningful role in developing the service array used in their recovery plan. Recovery houses are safe, healthy, family-like substance-free living environments that support individuals in recovery from addiction. Substance-free does not prohibit prescribed medications taken as directed by a licensed practitioner, such as pharmacotherapies specifically approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder as well as other medications with FDA-approved indications for the treatment of co-occurring health conditions. Recipients must describe the mechanism(s) in place in their jurisdiction to assure that a recovery housing facility to receive these funds supports and provides clients access to evidence-based treatment, including all forms of MOUD, in a safe and appropriate setting. Recipients must also describe how recovery housing supported under this grant is in an appropriate and legitimate facility (e.g., state or other credentialing or certification or an established or recognized model).

- Implement prevention and education services including:

- Training of peers, first responders, and other key community sectors on recognition of opioid overdose and appropriate use of the opioid overdose antidote naloxone;
- Developing evidence-based community prevention efforts such as strategic messaging on the consequences of opioid and stimulant misuse;
- Implementing school-based prevention programs and outreach; and
- Purchasing and distributing the opioid overdose antidote reversal naloxone, based on the naloxone distribution and saturation plan, and train on its use.

- Provide harm reduction services, either through support of integrated harm reduction services singly within treatment settings, treatment providers collaborating with community-based harm reduction organizations, or through the support of syringe service programs.[5] Harm reduction services funded under this grant must adhere to federal, state, and local laws, regulations, and other requirements related to such programs or services.[6]

- Ensure that all practitioners who serve clients with substance use disorders and are eligible to obtain a DATA waiver, employed by an organization receiving funding through SOR, receive such a waiver. The educational requirements for this waiver necessary to treat more than 30 patients at one time may be completed at no cost to the grant via pcssnow.org.

- Provide treatment transition and coverage for individuals reentering communities from criminal justice settings or other rehabilitative settings.

- Make use of the SAMHSA-funded SOR/Tribal Opioid Response Technical Assistance/Training (TA/T) resources to assist in providing training and technical assistance on evidence-based practices to healthcare providers and others in your state who will render services to individuals with OUD and/or stimulant use disorders.

---

[5] Consolidated Appropriations Act, 2022 (Public Law 117-103) Section 807, notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with state and local law.

[6] 21 U.S.C. §863(a) states:
[I]t is unlawful for any person to sell or offer for sale drug paraphernalia; to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or to import or export drug paraphernalia." The term "drug paraphernalia" is defined as "any equipment, product, or material of any kind which is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under this subchapter." 21 U.S.C. §863(d).

- Provide HIV and viral hepatitis testing as clinically indicated and referral to appropriate treatment provided to those testing positive. Vaccination for hepatitis A and B should be provided or referral made for same as clinically indicated.

4. ALLOWABLE ACTIVITIES

Allowable activities are an allowable use of grant funds but are not required. Recipients may use grant funds to provide any allowable activity if it does not interfere or prevent the grant recipient from performing all required activities and serve the total number of unduplicated individuals each year of the grant. Allowable activities may include:

- Develop and implement evidence-based prevention, treatment, and recovery support services to address stimulant misuse and use disorders, including for cocaine and methamphetamine. Clinical treatment may include outpatient, intensive outpatient, day treatment, partial hospitalization, or inpatient/residential levels of care.

- Purchase and/or implement mobile and/or non-mobile medication units that provide appropriate privacy and adequate space to administer and dispense medications for OUD treatment in accordance with federal regulations[7]. The following services may be provided in mobile medication units, assuming compliance with all applicable federal, state, and local law:

  o Administering and dispensing medications for opioid use disorder treatment;
  o Collecting samples for drug testing or analysis;
  o Dispensing of take-home medications;
  o Conducting intake/initial psychosocial and appropriate medical assessments, with a full physical examination to be completed or provided within 14-days of admission, in units that provide appropriate privacy and adequate space;
  o Initiating methadone or buprenorphine after an appropriate medical assessment has been performed; and
  o Counseling and other services, in units that provide appropriate privacy and have adequate space, may be provided directly or when permissible through use of telehealth services. Non-mobile medication units may also offer the above services where space allows for quality patient care and are consistent with state and local laws and regulations.

- Purchase and distribution of fentanyl test strips (FTS).

---

[7] Letter to OTP Directors, SOTAs and State Directors from Kimberly Nelson, Acting Director of CSAT https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf
Letter to State Substance Abuse Director on the adoption of mobile medication units from Miriam Delphin-Rittmon, Assistant Secretary for SAMHSA https://www.samhsa.gov/sites/default/files/2021-letter-state-authorities-mobile.pdf

- Develop and implement evidence-based contingency management programs to treat stimulant use disorder and concurrent substance misuse, and to improve retention in care. If you plan to implement contingency management programs, you must certify that you will comply with the conditions and training requirements, as well as provide a plan to ensure: (1) that sub-awardees receive appropriate education on contingency management prior to implementation; and (2) oversight of sub-awardee contingency management implementation and operation, as outlined in Appendix J of this NOFO. This Statement of Certification must be provided in **Attachment 10** of your application. However, the plan must be submitted **within 90 days of the grant award**.

- Provide training and activities to enhance and expand the substance use and co-occurring substance use and mental disorder treatment workforce. Note: Although workforce development is an allowable use of grant funds, SAMHSA expects that priority will be given to service provision and prevention activities. Recipients will be expected to utilize the training and education resources which SAMHSA provides at no cost to the grant.

- Develop and implement tobacco/nicotine product (e.g., vaping) cessation programs, activities, and/or strategies.

Administrative Costs and Infrastructure Development

Although services grant funds must be used primarily for direct services, SAMHSA recognizes that:

- o There are administrative costs associated with administering the SOR grant; and
- o Infrastructure changes may be needed to implement the services or improve their effectiveness.

You may use **no more than 5 percent** of the total grant award for the budget period for administrative costs (indirect cost) and the types of infrastructure development listed below, if necessary, to support the direct service expansion of the grant project. You must describe in Section B of your Project Narrative the use of grant funds for infrastructure activities which may include:

- Adopting and/or enhancing your computer system, management information system (MIS), electronic health records (EHRs), etc., to document and manage client needs, care process, integration with related support services, and outcomes.
- Training/workforce development to help project staff administer the grant program.

- Policy development to support needed service system improvements (e.g., rate-setting activities, establishment of standards of care, adherence to the [Behavioral Health Guide for the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care](#), development/revision of credentialing, licensure, or accreditation requirements)[8]

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. If an EBP(s) exists for the population(s) of focus and types of problems or disorders being addressed, the expectation is that EBP(s) will be utilized. If one does not exist but there are evidence-informed and/or culturally promising practices that are appropriate or can be adapted, these interventions may be implemented in the delivery of services.

In your Project Narrative, in response to [Section C](#) of Section V of this NOFO, you will need to identify the evidence-based practice(s) and/or interventions that are evidence-informed and/or culturally promising that are appropriate or can be adapted to meet the needs of your specific population(s) of focus. You must discuss the population(s) for which the practice(s) has (have) been shown to be effective and document that it is (they are) appropriate for your population(s) of focus. You must also address how these interventions will improve outcomes and address how you will monitor and ensure fidelity of EBPs and other appropriate interventions.

Applicants are encouraged to visit the [SAMHSA Evidence-Based Practice Resource Center](#) and [SAMHSA's National Network to Eliminate Disparities in Behavioral Health](#) to identify evidence-informed and culturally appropriate mental illness and substance use prevention and treatment practices that can be implemented in your project.

---

[8] For purposes of this NOFO efforts do not include activities designed to influence the enactment of legislation, appropriations, regulations, administrative actions, or Executive Orders ("legislation and other orders") proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, and awardees may not use federal funds for such activities. This restriction extends to both grassroots lobbying efforts and direct lobbying. However, for state, local, and other governmental recipients, certain activities falling within the normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government are not considered impermissible lobbying activities and may be supported by federal funds.

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 E: Data Collection and Performance Measurement in Section V of this NOFO.

Recipients are required to report performance on the following measures: abstinence, employment/education status, criminal justice involvement, social connectedness, health/behavioral/social consequences, and housing stability. Recipients will be required to report client-level data on elements including but not limited to demographic characteristics, substance use, diagnosis(es), services received, and types of MOUD received (see Appendix C- Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines, 4. Data Collection).

This information will be gathered using a uniform data collection tool provided by SAMHSA. Recipients are required to submit data via SAMHSA's Performance Accountability and Reporting System (SPARS); and access will be provided upon award. An example of the required data collection tool can be found at https://www.samhsa.gov/sites/default/files/csat-gpra-client-outcomes-measures-tool.pdf. Data will be collected at intake to services, six months post intake, and at discharge. Recipients will be expected to do a GPRA interview on all clients in their specified unduplicated target number and are also expected to achieve a six-month follow-up rate of 80 percent.

Recipients should enter their data within 1 day—but no later than 7 days—after the GPRA interview is conducted. This guidance applies to recipients who manually enter their data and batch upload their data.

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 behavioral health access, service use, and outcomes nationwide. As a result, SAMHSA may add additional reporting measures throughout the reporting period to meet these needs.

Recipients will also be required to report program-level data on a quarterly basis in SPARS. The SOR/TOR – Program Instrument will collect the following measures:

- Naloxone overdose kits purchase and distribution
- Overdose reversal

- Fentanyl test strips purchase and distribution
- Education of school-aged children, first responders, and key community sectors on opioid and/or stimulant misuse
- Outreach activities that target underserved and/or diverse populations

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

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

No more than 5 percent of the total grant award for the budget period may be used for data collection, performance measurement, and performance assessment, including incentives for participating in the required data collection follow-up.

Note: See Appendix D and Appendix E of this NOFO for more information on responding to this section.

7. OTHER EXPECTATIONS

SAMHSA Values That Promote Positive Behavioral Health

SAMHSA expects recipients to use grant funds to implement high quality programs, practices, and policies that are recovery-oriented, trauma-informed, and equity-based as a means of improving behavioral health.[9]

Recovery is a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Recovery oriented recipients promote partnerships with people in recovery from mental and substance use disorders and their family members to guide the behavioral health system and promote individual, program, and system-level approaches that foster:

---

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

Health—managing one's illnesses or symptoms and making informed healthy choices that support physical and emotional wellbeing; *Home*—a stable and safe place to live; *Purpose*—meaningful daily activities such as a job or school; and *Community*—supportive relationships with families, friends and peers. Recovery oriented systems of care embrace recovery as: emerging from hope; person-driven; occurring via many pathways; holistic; supported by peers and allies; culturally-based and influenced; supported through relationship and social networks; involving individual, family, and community strengths and responsibility; supported by addressing trauma; and based on respect.

Trauma-informed care recognizes and intentionally responds to the lasting adverse effects of experiencing traumatic events. Trauma-informed care is defined through six key principles: *Safety*: participants and staff feel physically and psychological safe; *Peer support:* peer support and mutual self-help as vehicles for establishing safety and hope, building trust, enhancing collaboration, and utilizing their lived experience; *Trustworthiness and Transparency*: decisions are conducted with the goal of building and maintaining trust; C*ollaboration and Mutuality:* importance is placed on partnering and leveling power differences; *Cultural, Historical, & Gender Issues*: culture and gender-responsive services are offered while moving beyond stereotypes/biases; and *Empowerment, Voice and Choice*: organizations foster a belief in the primacy of the people who are served to heal and promote recovery from trauma.[10]   It is critical recipients promote the linkage to recovery and resilience for those individuals and families impacted by trauma.

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

Coordination with Other Federal Programs

If your state or territory currently receives opioid-related funding from other Federal programs, you must coordinate activities to eliminate duplication of services and programs (e.g., SAMHSA MAT-PDOA, SPF-Rx, PDO, SABG, CDC's Opioid Prevention in States, etc.).

---

[10] https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf

The Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of care that includes primary medical care and essential support services for people living with HIV who are uninsured or underinsured. Recipients are encouraged to collaborate and coordinate with RWHAP recipients for the provision of HIV care and treatment services, including Hepatitis screening, testing, and vaccination for people living with HIV.

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).

Third Party Reimbursements for the Provision of Services/Health Insurance Enrollment

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, returning veterans, and military families in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

8. GRANTEE MEETINGS

Recipients must send a maximum of two people (including the Project Director) to at least one joint grantee meeting. For this cohort, the grantee meetings will be held in year one of the grant. You must include a detailed budget and narrative for this travel in your budget. At these meetings, recipients will present the results of their projects and federal staff will provide technical assistance. The meeting will be up to two days. These meetings are usually held in the Washington, D.C. metropolitan area. If SAMHSA elects to hold a virtual meeting, budget revisions will be permitted.

II.   FEDERAL AWARD INFORMATION

1. GENERAL INFORMATION

Funding Mechanism: Grant

Estimated Total Available Funding: $1,439,500,000

Estimated Number of Awards: 59

Estimated Award Amount: See Appendix K for estimated award amounts

Length of Project Period: Up to 2 years

Anticipated Start Date: September 30, 2022

SOR grants are awarded via a formula. Each State, as well as the District of Columbia, will receive not less than $4,000,000. Each territory will receive not less than $250,000.

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.

Applicants should be aware that funding amounts are subject to the availability of funds.

III.   ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are the Single State Agencies for Substance Use Services in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia. Tribes/Tribal Nations are eligible to apply for opioid response funding under a separate announcement.

2. COST SHARING AND MATCHING REQUIREMENTS

Cost sharing/match is not required in this program.

3. OTHER REQUIREMENTS

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

- **Evidence of Experience and Credentials**

  SAMHSA believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide the required services quickly and effectively. All Required Activities must be provided by applicants directly, by subrecipients, or through referrals to applicant partner agencies. Applicants must submit documentation in **Attachment 1** of their application that they meet three additional requirements related to the provision of services.

  The three requirements are:

  o Provider organizations for direct client services (e.g., substance use/mental disorder treatment) appropriate to the grant must be involved in the proposed project. The provider may be the applicant, or another organization committed to the project. More than one provider organization may be involved.

  o Each substance use/mental disorder treatment provider organization must have at least two years of experience (as of the due date of the application) providing relevant services.

  o Each substance use/mental disorder treatment provider organization must comply with all applicable federal, local (city, county) and state licensing, accreditation, and certification requirements, as of the due date of the application.

  The above requirements apply to all service provider organizations.

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 Appendix A - 2.2 Required Application Components of this NOFO.

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

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

- **SF-424** – Fill out all Sections of the SF-424.
  - In **Line #4** (i.e., Applicant Identifier), input the Commons Username of the PD/PI.
  - In **Line #17** input the following information: (Proposed Project Date: a. Start Date: 9/30/2022; b. End Date: 9/29/2024).

- **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: Use the first row only (Line 1) to report the total federal funds (e) and non-federal funds (f) requested for the first year of your project only.

  - **Section B** – Budget Categories: Use the first column only (Column 1) to report the budget category breakouts (Lines 6a through 6h) and indirect charges (Line 6j) for the total funding requested for the first year of your project only.

  - **Section C** – Leave blank if cost sharing/match is not required for this program. Complete if cost sharing/match is required.

  - **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 for non-federal funds.

  - **Section E** – Budget Estimates of Federal Funds Needed for Balance of the Project: Input the total funds requested for the out year (e.g., Year 2). For example, if you are requesting funds for two years in total, you would input information in column b (i.e., one out year).

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

    A link to a sample budget form and justification is included in **Appendix I** 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 Section V.1 – Application Review Information.

- **BUDGET JUSTIFICATION AND NARRATIVE**
  The budget justification and narrative must be submitted as a file entitled "BNF" (Budget Narrative Form) when you submit your application into Grants.gov. (See Appendix A – 2.2 Required Application Components.)

- **ATTACHMENTS 1 THROUGH 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: Service Providers/Evidence of Experience and Credentials*
    Statement of Certification - You must provide a written statement certifying that all participating service provider organizations listed in this application meet the two-year experience requirement and applicable licensing, accreditation, and certification requirements.

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

  - *Attachment 3: Sample Consent Forms*
    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 Section V, B.3 of this NOFO.

o *Attachment 5: Biographical Sketches and Position Descriptions*
See Appendix F of this NOFO for information on completing biographical sketches and job descriptions. Position descriptions should be no longer than one page each and biographical sketches should be two pages or less.

o *Attachment 6: Confidentiality and SAMHSA Participant Protection/ Human Subjects Guidelines*
This attachment is in response to Appendix C of this NOFO and is **a required attachment.**

o *Attachment 7: 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.

o *Attachment 8: Needs Assessment*
This attachment is in response to Section I-1.3, Required Activities of this NOFO, and will be scored by reviewers (see Section V, A.2 of this NOFO). The Needs Assessment must include a Naloxone Distribution and Saturation Plan. The needs assessment should identify:
  ▪ The scope of OUD and substance use disorders and overdose mortality in recent years.
  ▪ The strengths, unmet service needs, and critical gaps in your service system across diverse racial, ethnic, geographic, and other demographic groups.
  ▪ Areas where opioid and stimulant misuse, substance use disorder, use of emergency medical resources for substance use such as hospitalization, and overdose are the most prevalent.
  ▪ The number and location of opioid treatment providers in the state, including Opioid Treatment Programs (OTPs) as well as DATA-waivered office-based opioid treatment providers.
  ▪ All existing activities and their funding sources in the state that address opioid and stimulant use prevention, harm reduction, treatment, and recovery activities and remaining gaps in these activities.

o *Attachment 9: Strategic Plan*
This attachment is in response to Section I-1.3, Required Activities of this NOFO, and will be scored by reviewers (see Section V, B.1 of this NOFO). The Strategic Plan must address the gaps in prevention, harm

reduction, treatment, and recovery services related to opioids and stimulants identified in the needs assessment.

Note: Attachments 8 and 9 combined are limited to a maximum of 10 pages.

- o *Attachment 10: Contingency Management*
  Statement of Certification – If you plan to implement contingency management with SOR funds, you must provide a written statement certifying that you will comply with the conditions and training requirements for contingency management as outlined in Appendix J of this NOFO.

3. UNIQUE ENTITY IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT

See Appendix A for information about the four registration processes that must be completed including obtaining a Unique Entity Identifier and registering with the System for Award Management (SAM). You must continue to maintain an active SAM registration with current information during the 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 **July 18, 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 Appendix A of this NOFO 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 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 below. Be sure to identify these expenses in your proposed budget.

- No more than 5 percent of the total grant award for the budget period may be used for administrative costs (i.e., indirect cost) and developing the infrastructure necessary for expansion of services.

- No more than 5 percent of the total grant award for the budget period may be used for data collection, performance measurement, and performance assessment, including incentives for participating in the required data collection follow-up.

- Only U.S. Food and Drug Administration (FDA) – approved products that address opioid use disorder and/or opioid overdose can be purchased with Opioid SOR grant funds.

- Funds may not be expended through the grant or a subaward by any agency which would deny any eligible client, patient or individual access to their program because of their use of FDA-approved medications for the treatment of

substance use disorders (e.g., methadone, buprenorphine products including buprenorphine/naloxone combination formulations and buprenorphine monoproduct formulations, naltrexone products including extended-release and oral formulations or long acting products such as extended release injectable or buprenorphine.) Specifically, patients must be allowed to participate in methadone treatment rendered in accordance with current federal and state methadone dispensing regulations from an Opioid Treatment Program and ordered by a physician who has evaluated the client and determined that methadone is an appropriate medication treatment for the individual's opioid use disorder. Similarly, medications available by prescription or office-based implantation must be permitted if it is appropriately authorized through prescription by a licensed prescriber or provider. In all cases, MOUD must be permitted to be continued for as long as the prescriber or treatment provider determines that the medication is clinically beneficial. Recipients must assure that clients will not be compelled to no longer use MOUD as part of the conditions of any programming if stopping is inconsistent with a licensed prescriber's recommendation or valid prescription.

- No funding may be used to procure DATA waiver training by recipients or subrecipients of this funding.

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

6. OTHER SUBMISSION REQUIREMENTS

See Appendix A for specific information about submitting your application.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

The Project Narrative describes what you intend to do with your project and includes the Evaluation Criteria in Sections A-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 five sections/headings listed below in developing your Project Narrative. **You must indicate the Section letter and number in your response**, **i.e.**, **type "A-1", "A-2", etc., before your response to each question.** You do not need to type the full criterion in each section. You only need to include the letter and number of the criterion. You may not combine two or more questions or refer to another section of the Project Narrative in your

response, such as indicating that the response for B.2 is in C.1. **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 questions, each question 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 of Focus and Statement of Need
(15 points – approximately 1 page [not including Attachment 8- Needs Assessment])

1. Identify and describe your population(s) of focus and the geographic catchment area where services will be delivered that align with the intended population of focus of this program. Provide a demographic profile of the population of focus in the catchment area in terms of race, ethnicity, federally recognized tribe (if applicable), language, sex, gender identity, sexual orientation, age, and socioeconomic status. Discuss whether funding will also be used to address stimulant misuse.

2. Based on your Needs Assessment, describe the extent of the problem in the catchment area, including service gaps, and document the extent of the need (i.e., current prevalence rates or incidence data) for the population(s) of focus identified in your response to A.1. Identify the source of the data.

   In **Attachment 8***, provide your Needs Assessment. It must include the required elements for the Needs Assessment outlined in Section I-1.3- Required Activities.

SECTION B: Proposed Implementation Approach
(30 points – approximately 5 pages [not including Attachment 9 – Strategic Plan and Attachment 4 – Project Timeline])

1. Describe the goals and measurable objectives (see Appendix D) of the proposed project and align them with the Statement of Need described in A.2., as well as your Strategic Plan. In **Attachment 9***, provide your Strategic Plan. It must address the required elements outlined in Section I-1.3- Required Activities. Provide the following table:

Number of Unduplicated Individuals to be Served with Grant Funds		
	Year 1	Year 2	Total

Treatment Services**			
Recovery Support Services**			
Prevention Services			
GPRA/SPARS Target**			

*Note: Attachments 8 and 9 combined must not exceed 10 pages.

**Note: Of those individuals receiving treatment and recovery support services, applicants must indicate the total number of individuals who will complete the CSAT Government Performance and Results Act (GPRA) Client Outcome Measures for Discretionary Programs Tool for each grant year; the total receiving treatment and recovery support services will be the applicant's GPRA target in SPARS.

2. Describe how you will implement all of the Required Activities in Section I. If you plan to use funds for infrastructure development, you must describe how the funds will be used.

3. In **Attachment 4**, provide a chart or graph depicting a realistic timeline for the entire two years of the project period showing dates, key activities, and responsible staff. These key activities must include the requirements outlined in Section I [**NOTE**: Be sure to show that the project can be implemented, and service delivery can begin as soon as possible and no later than three 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 C: Proposed Evidence-Based Service/Practice
(25 points approximately 2 pages)

1. Identify the Evidence-Based Practice(s) (EBPs), evidence-informed, and/or culturally promising practices that will be used. Discuss how each intervention chosen is appropriate for your population(s) of focus and the outcomes you want to achieve. Describe any modifications that will be made to the EBP(s) and the reason the modifications are necessary. If you are not proposing any modifications, indicate so in your response. interventions.

2. Describe how you will monitor and ensure fidelity of EBPs, evidence-informed and/or promising practices that will be implemented.

SECTION D: Staff and Organizational Experience
          (10 points – approximately 1 page)

1. Describe the experience of your organization with similar projects and/or providing services to the population(s) of focus for this NOFO. Identify other organization(s) that you will partner with in the proposed project. Describe their experience providing services to the population(s) of focus, and their specific roles and responsibilities for this project.

2. Provide a complete list of staff positions for the project, including the Key Personnel (Project Director, Project Coordinator, and Data Coordinator) and other significant personnel. Describe the role of each, their level of effort, and qualifications, to include their experience providing services to the population(s) of focus and familiarity with their culture(s) and language(s).

SECTION E: Data Collection and Performance Measurement
          (20 points – approximately 1 page)

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

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

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

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

A link to a budget and narrative justification is included in Appendix I – Sample Budget and Justification. **It is highly recommended that you use this sample budget format.** Your proposed budget must reflect the funding limitations/restrictions specified in Section IV-5. **Specifically identify the items associated with these costs in your budget**.

3. REVIEW AND SELECTION PROCESS

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

Decisions to fund a grant are based on:

The strengths and weaknesses of the application as identified by peer reviewers. The results of the peer review are advisory in nature.

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

- A formula using national survey results that the Secretary determines are the most objective and reliable measure of drug use and drug-related deaths; states with the highest mortality rate related to opioid use disorders will receive a 15 percent set-aside.
- Individual award is over $250,000, approval by the or Center for Substance Abuse Treatment 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;
- 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, FAPIIS]. You may review and comment on any information about your organization that a federal awarding agency previously entered. SAMHSA will consider your comments, in addition to other information in 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 Notice of Award (NoA) will be emailed to the following: 1) the BO's email address identified in the Authorized Representative section email field on page 3 of the SF-424; and 2) the email associated with the Commons account for the Project Director (section 8 Item f on page 1 of the SF-424). Hard copies of the NoA will no longer be mailed via postal service. The NoA is the sole obligating document that allows you to receive federal funding for work on the 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 - . https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions. See Appendix H for specific information about administrative and national policy requirements.

3. REPORTING REQUIREMENTS

You will be required to submit semi-annual reports (at 6 months and 12 months). The six-month report is due no later than 30 days after the end of the second quarter. The annual report is due within 90 days of the end of the budget period. The report must discuss:

- Major accomplishments for each of your approved activities (i.e., prevention, harm reduction, treatment, and recovery support). Include outcomes data for each activity;
- Barriers and your efforts to overcome them;
- Progress achieved in addressing the needs of diverse populations (e.g., racial/ethnic minorities, LGBTQ+, older adults) and implementation of targeted interventions to promote behavioral health equity; and
- Administrative/Infrastructure and Data Collection costs to ensure the costs are compliant and do not exceed the caps.

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.

4. 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 NoA.

VII. AGENCY CONTACTS

For program related and eligibility questions contact:

C. Danielle Johnson Byrd, MPH
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
(240) 276-0300
OPIOIDSOR@samhsa.hhs.gov

For fiscal/budget related questions contact:

Office of Financial Resources, Division of Grants Management
Substance Abuse and Mental Health Services Administration
OPIOIDSOR@samhsa.hhs.gov

For grant review process and application status questions contact:

Sara Fleming
Office of Financial Resources, Division of Grant Review
Substance Abuse and Mental Health Services Administration
(240) 276-1693
sara.fleming@samhsa.hhs.gov

Appendix A – Application and Submission Requirements

1.   GET REGISTERED

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

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

NOTE: Prior to April 4, 2022, there were four components of the registration process which included obtaining a Dun and Bradstreet Number (DUNS number). The DUNS number has been replaced by a new Unique Entity Identifier (UEI) which is assigned by SAM.

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

You must register in eRA Commons and receive a Commons Username in order to have access to electronic submission, receive notifications on the status of your application, and retrieve 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   System for Award Management Registration

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

You must continue to maintain active SAM registration with current information during the 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.

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.

1.2   Grants.gov Registration

Grants.gov 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.

1.3   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 Institution Registration Form. 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
1	SF-424 (Application for Federal Assistance) Form	This form must be completed by applicants for all SAMHSA grants. 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 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 the Signing Official/Business Official (SO/BO).	Grants.gov/forms

#	Standard Application Components	Description	Where to Find Document
2	SF-424 A (Budget Information – Non-Construction Programs) Form	Use SF-424A. Fill out Sections A, B, D and E of the SF-424A. Section C should only be completed if applicable. **It is highly recommended that you use the budget template.**	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.	
5	Project Narrative Attachment	The Project Narrative is your response to the Evaluation Criteria found at Section V of this NOFO. It cannot be longer than 15 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	

#	Standard Application Components	Description	Where to Find Document
		additional/supporting documents listed in the table below.	

Supporting Documents

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

#	Supporting Documents	Description	Where to Find Document
1	HHS 690 Form	Every 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 7)	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 F of this document for additional instructions for completing these sections. Formatting requirements outlined in Appendix B are not applicable for these documents.	Appendix F of this document.
4	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 6)	See the NOFO or requirements related to confidentiality, participant protection, and the protection of human subject's regulations.	NOFO: See Appendix C
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: eRA Modules, User Guides, and Documentation | Electronic Research Administration (eRA)

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

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

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

3.2   Waiver from Electronic Submission

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

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

Direct any questions regarding the submission waiver process to the Division of Grant Review at 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 e-mails from Grants.gov within the next 24-48 hours (one notification email will confirm receipt of the application in Grants.gov, and the other notification email will indicate that the application was either successfully validated by the Grants.gov system or rejected due to errors). It is important that you retain this Grants.gov tracking number. **Receipt of the Grants.gov tracking number is the only indication that Grants.gov has successfully received and validated your application.** If you do not receive a Grants.gov tracking number, you may want to contact the Grants.gov help desk for assistance (see Resources for Assistance in Section 3.4).

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

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

If errors are found during eRA Commons validation, you will receive a System Error and/or Warning notification regarding the problems found in the application (see 4.2 below). You must take action to make the required corrections and resubmit the application through Grants.gov before the application due date and time. 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 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 **one business day after the official due date at:** dgr.applications@samhsa.hhs.gov and provide the following:

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

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

[Note: When resubmitting an application after revisions have been made, ensure that the **Project Title is identical to the Project Title in the originally submitted**

application (i.e., no extra spacing) as the Project Title is a free-text form field.] In addition, check the Changed/Corrected Application box in #1.

Appendix B - Formatting Requirements and System Validation

1. SAMHSA FORMATTING REQUIREMENTS

SAMHSA's goal is to review all applications submitted for 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 must be 'error free' to be processed through the eRA Commons. There may be additional validations which will result in Warnings but these will not prevent the application from processing through the submission process. (See Appendix A, Section 4.2)

ASSIST File Formatting Requirements

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

Files for Upload to ASSIST must be:

- ☑ PDF Format

- ☑ Under 6MB in File Size

- ☑ 8.5 x 11 Page Size

- ☑ Flat *(No Fillable/Editable Fields)*

Files must **NOT** contain:

- ☒ Password-Protection

- ☒ Live hyperlinks *(only plain text URLs)*

- ☒ Bookmarks or Signature Boxes

- ☒ A filename exceeding 50 Characters *(including spaces)*

Flatten Fillable Forms Prior to Upload in ASSIST

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

Flattening a PDF document:

- **Keeps form values permanent.** When an interactive PDF is uploaded or emailed, every field remains open to accidental or deliberate revision. Flattening the form ensures that only the completed version of the form is visible.

- **Removes values on drop down lists.** A flattened document will show only the selected text or value, no other values and options are shown and there is no indication that options were present.

- **Simplifies the PDF.** Interactive forms are larger than normal files, which may prevent upload for submission. Flattening reduces the file size which makes it easier to render and view.

To flatten a file, follow the steps below.

1. Ensure that the form is completed and the information is correct. Go to the print settings by selecting **File > Print**.

2. On the pull-down menu of printer options, choose Adobe PDF or Microsoft Print to PDF, then click OK.

3. After clicking **OK,** a pop-up will open with options to save the PDF. Be sure to select a specific location to save the document where it can easily be found and give it a unique file name. Use a file name that clearly differentiates the completed form from the original fillable form. File names cannot exceed 50 characters.

4. The flattened form should appear in the new location with the new file name. Open it to check once more for any changes and to confirm that the conversion worked.

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

eRA Commons Validation Table

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

eRA Validations	eRA Error Messages
#1: Applicant Identifier (Item 4 on the SF-424): The PD/PI Credentials must be provided Username provided must be a valid Commons account Username must be affiliated with the organization submitting the application and or have the PI role	The Commons Username must be provided in the Applicant Identifier field for the PD/PI. The Commons Username provided in the Applicant Identifier is not a recognized Commons account. 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_guidelines.htm."
#8. All attachments must comply with the following formatting requirements: PDF attachments cannot be empty (0 bytes).	The {attachment} attachment was empty. PDF attachments cannot be empty, password protected or encrypted.

eRA Validations	eRA Error Messages
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>.
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/pdf_guidelines.htm
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.
#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) 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 Federal Total for 1st year, in Section D- Forecasted Needs equals the Section A, New or Revised Budget Federal Totals (e-5) amount. 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 – 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 6 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 incentive may be provided 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:

  o Where data will be stored,

  o Who will have access to the data collected, and

  o 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 **Title 42 of the Code of Federal Regulations, Part II, Subpart B.**

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 D – 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

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

The characteristics of effective goals include:

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

Examples

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

OBJECTIVES

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

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

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

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

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

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

Time-bound –
Provide a time frame indicating when the objective will be measured or a time by when the objective will be met. For example, "Five new peer educators will be recruited by the second quarter of the first funding year" is a better objective than "New peer educators will be hired."

Examples:

Non-SMART Objective	Critique	SMART Objective
Teachers will be trained on the selected evidence-based substance use 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 use 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 use and HIV prevention curriculum.***
Train individuals in the community on the prevention of prescription drug/opioid overdose-related deaths.	This objective is not SMART as it is not *specific, measurable* or *time-bound*. It can be made SMART by specifically indicating *who* is responsible for the training, *how many* people will be trained, *who* they are, and by *when* 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 E – 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 E 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.

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

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

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

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

Data Management

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 F – 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 G – 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 purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 C.F.R. 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase, or distribution of marijuana).

- Pay for promotional items including, but not limited to, clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags (See 45 CFR 75.421(e)(3)).

- Pay for the purchase or construction of any building or structure to house any part of the program. Minor alterations and renovations (A&R) may be authorized for up to $150,000 or 5% of the overall indirect costs (whichever is more) of a given budget period for existing facilities, if necessary and appropriate to the project. Minor A&R may not include a structural change (e.g., to the foundation, roof, floor, or exterior or loadbearing walls of a facility, or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change the function and purpose of the facility. All minor A&R must be approved by SAMHSA.

- 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, clients many not receive contingencies totaling more than $75 per budget period. **The contingency amounts are subject to change.**

- 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)

- 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 527, notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. Provided, that such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with state and local law.

- **Salary Limitation**: The Consolidated Appropriations Act, 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 $203,700. 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 H – Administrative and National Policy

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

HHS Grants Policy Statement (GPS)

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

HHS 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:

- o 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.
- o 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 2 CFR 200.202, 2 CFR 200.301 and 2 CFR 200.329) of the grant award, or in reduction or withholding of continuation awards.

Termination of Federal Award

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

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

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 Appendix I Sample Budget and Justification for additional indirect cost guidance.

Trafficking in Persons

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

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

Publications

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

- Provide the GPO with advance copies of publications.
- Include acknowledgment of the SAMHSA 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 use treatment/substance use prevention/mental health services community.

Appendix I – 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 detailed budget 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 Click here SAMHSA Forms and Resources – scroll down to "**SAMHSA Budget Template**" section. You **must** download the budget

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

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

Guidance

The following documents provide guidance on using the budget template:

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

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

Sample Budgets

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

- [Sample SF-424 - New Awards (PDF | 1.3 KB)](#)

- 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.

In **Section A** use rows 1–4 to provide the budget amounts for the first year 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 the first year of the project.

In **Section B**, use column (1) to provide category amounts for year one and use column (2), if applicable, for cost sharing/matching.

Section C – Non-Federal Resources: complete only if Section III. 2. Cost Sharing/Matching of the NOFO indicates that cost sharing/matching is required.

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

Personnel Costs: 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 **$203,700**. 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.

Fringe Benefits: 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.

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

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current

equipment must be provided when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of $5,000 or more and a useful life of one or more years). For example, large items of medical equipment.

Supplies: 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 UEI number (see 2 CFR part 25). For consultant services, list the total costs for all consultant services. In the budget narrative, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

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.

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

Appendix J – Contingency Management

To mitigate the risk of fraud and abuse, while also promoting evidence-based practice, recipients who plan to implement contingency management (CM) interventions as part of their SAMHSA grant award will be required to comply with the following conditions:

1. The type of CM model chosen will be consistent with the needs of the population of focus.

2. To ensure fidelity to evidence-based practice, staff who will implement, administer, and supervise CM interventions are required to undergo CM-specific training prior to implementing CM. Training should be delivered by an advanced degree holder who is experienced in the implementation of evidence-based contingency management activities. Training should be easily accessible, and it can be delivered live or through pre-recorded training sessions. When participants receive training through pre-recorded sessions, they should have an opportunity to pose questions and to receive responses in a timely manner.

   Education must include the following elements:
   o The core principals of contingency management
   o Target behavior;
   o The population of focus;
   o Type of reinforcer (incentive);
   o Magnitude (or amount) of reinforcer;
   o Frequency of reinforcement distribution;
   o Timing of reinforcement distribution; and,
   o Duration reinforcement(s) will be used
   o How to describe contingency management to eligible and ineligible patients
   o Evidence-based models of contingency management and protocols to ensure continued adherence to evidence-based principles
   o The importance of evidence-based practice on patient outcomes
   o Testing methods and protocols for target substance use disorders and/or behaviors
   o Allowable incentives, appropriate selection of incentives, storage of incentives, the distribution of incentives, and immediacy of awards
   o Integration of contingency management into comprehensive clinical activities and program design. Contingency management should be integrated into services, counseling and treatment activities that provide ongoing support to the clients
   o Documentation standards
   o Roles and responsibilities, including the role of the supervisor, decision maker, and direct care staff
   o Techniques for supervisors to provide on-going oversight and coaching

Within **90 days of grant award**, you must submit your plan to ensure: (1) that sub-awardees receive appropriate education on contingency management prior to implementation; and (2) oversight of sub-awardee contingency management implementation and operation.

The CM Incentive is offered or furnished pursuant to an evidence-based CM intervention.

3. The recipient's organization must maintain written documentation in the patient's medical record that includes:

   I.   The type of CM model and incentives offered that are recommended by the client's licensed health care professional;
   II. A description of the CM incentive furnished;
   III. An explanation of the health outcome or target behavior achieved; and
   IV. A tally of incentive values received by the patient to confirm that per incentive and total incentive caps are observed.

4. Receipt of the CM Incentive is contingent upon achievement of a specified target behavior, consistent with the beneficiary's treatment plan that has been verified with objective evidence.

5. The CM Incentive is recommended by the client's treating clinician, who is licensed under applicable state law.

6. The CM Incentive is not cash, but may be tangible items, vouchers, or payment of bills that are of equivalent value to the individual's total or accrued incentive earnings.

7. No person markets the availability of a CM Incentive to induce a patient to receive federally reimbursable items or services or to receive such items and services from a particular provider or supplier.

Appendix K – Annual Formula Based Allocation of State Opioid Response Grants

Note: If all states do not apply, funds remaining will be redistributed to all grantees. The "Annual Award Amount" column displays the MAXIMUM dollar amount PER YEAR for which a state/territory can apply. The project period is two years. Funding availability and allocation for the second year are contingent upon Congressional appropriations and direction.

SAMHSA recognizes that COVID-19 has had significant impacts not only on the overdose crisis but also on states' ability to respond in the midst of significant disruptions and changes brought about by the pandemic. SAMHSA will monitor and evaluate updated data to assess impact. In FY 2022, SAMHSA is carrying forward the formula and data which is based on two elements weighted equally: the state's proportion of drug overdose deaths (CDC) and the state's proportion of people who meet diagnostic criteria for dependence or abuse of heroin or pain relievers who report not having received any treatment (NSDUH). Each State, as well as the District of Columbia will receive not less than $4,000,000. Each territory will receive not less than $250,000. The allocation continues the 15 percent set-aside for states with the highest overdose mortality rates. For the FY 2022 allocation, this set aside is distributed across 10 states (WV, DE, MD, PA, OH, NH, DC, NJ, MA, KY) based on an ordinal ranking.

STATE	FY 2022 ANNUAL AWARD AMOUNT
Alabama	$16,264,369
Alaska	$4,000,000
American Samoa	$250,000
Arizona	$31,956,846
Arkansas	$10,880,435
California	$107,038,177
Colorado	$21,073,833
Connecticut	$14,372,802
Delaware	$37,282,640
District of Columbia	$24,138,227
Florida	$101,280,912
Georgia	$29,600,797

STATE	FY 2022 ANNUAL AWARD AMOUNT
Guam	$250,000
Hawaii	$4,000,000
Idaho	$7,936,034
Illinois	$37,187,828
Indiana	$29,141,538
Iowa	$9,081,141
Kansas	$8,368,788
Kentucky	$35,912,100
Louisiana	$17,453,830
Maine	$6,325,323
Marshall Islands	$250,000
Maryland	$51,378,523
Massachusetts	$57,638,812
Michigan	$36,844,904
Micronesia	$250,000
Minnesota	$11,354,964
Mississippi	$7,241,395
Missouri	$25,295,012
Montana	$4,000,000
Nebraska	$4,491,855
Nevada	$16,719,861
New Hampshire	$28,505,671
New Jersey	$66,745,336
New Mexico	$7,617,237
New York	$56,858,435
North Carolina	$35,539,042
North Dakota	$4,000,000

STATE	FY 2022 ANNUAL AWARD AMOUNT
Northern Mariana Islands	$250,000
Ohio	$97,354,086
Oklahoma	$16,150,480
Oregon	$15,470,977
Palau	$250,000
Pennsylvania	$80,772,375
Puerto Rico	$12,160,000
Rhode Island	$7,442,546
South Carolina	$18,138,356
South Dakota	$4,000,000
Tennessee	$30,451,167
Texas	$52,772,628
Utah	$10,839,983
Vermont	$4,000,000
Virgin Islands	$250,000
Virginia	$27,947,054
Washington	$27,475,037
West Virginia	$44,335,111
Wisconsin	$16,913,533
Wyoming	$4,000,000