

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

FY 2011 Supplements for Rapid HIV Testing

(Short Title: RHT Supplements)

(Initial Announcement)

Request for Applications (RFA) No. TI-11-015

Catalogue of Federal Domestic Assistance (CFDA) No.: 93.243

Key Dates:

Application Deadline	Applications are due by June 1, 2011.
Intergovernmental Review (E.O. 12372)	Applicants must comply with E.O. 12372 if their State(s) participates. Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination	Applicants must send the PHSIS to appropriate State and local health agencies by application deadline. Comments from Single State Agency are due no later than 60 days after application deadline.

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the availability of funds to expand the capacity of Minority AIDS Initiative (MAI) grantees in the Center for Substance Abuse Treatment (CSAT)) and Center for Substance Abuse Prevention (CSAP) to provide rapid HIV testing, counseling and referral to care.

Funding Opportunity Title:	RHT Supplements
Funding Opportunity Number:	TI-11-015
Due Date for Applications:	June 1, 2011
Anticipated Total Available Funding:	\$2.25 million
Estimated Number of Awards:	Up to 45
Estimated Award Amount:	Up to \$50,000 per year
Cost Sharing/Match Required	No
Length of Project Period:	1 year
Eligible Applicants:	FY 2007 CSAT MAI grantees and FY 2008, 2009, and 2010 CSAP MAI grantees. [See Section III-1 of this RFA for complete eligibility information.]

I. FUNDING OPPORTUNITY DESCRIPTION

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the availability of funds to expand the capacity of Minority AIDS Initiative (MAI) grantees in the Center for Substance Abuse Treatment (CSAT) and Center for Substance Abuse Prevention (CSAP) to provide rapid HIV testing, counseling, and referral to care.

The RHT Supplements will promote the principle goals of the MAI which are to improve HIV-related health outcomes for racial and ethnic minority communities disproportionately affected by HIV/AIDS and reduce HIV related health disparities. In addition, the RHT Supplements are aligned with the objectives of the National HIV/AIDS Strategy (NHAS) to: 1) reduce the number of people who become infected with HIV, 2) increase access to care and optimize health outcomes, and 3) reduce HIV-related health disparities. Intensifying HIV prevention efforts with the utilization of rapid HIV testing of individuals with substance use and/or mental disorders is also consistent with the NHAS, given the disproportionately high prevalence of HIV among ethnic and racial minorities.

The goals and objectives of the MAI, NHAS, and RHT Supplements are consistent with the goals of the Affordable Care Act (Strategic Initiative #5 - Health Reform), which emphasizes the coordination of services for federally funded health service agencies to provide comprehensive care to the needs of vulnerable populations.

There is a critical need to increase testing activities among individuals who are at risk for HIV, and especially those who are not aware of their sero-status. The HIV epidemic has been documented to be larger than previously estimated. In 2008, the Centers for Disease Control and Prevention (CDC) with the use of new technology estimated that approximately 56,300 new HIV infections occurred in the U.S. in 2006, a figure that is 40% higher than CDC's former estimate of 40,000 new infections per year. These new estimates indicate that there are about 1,106,400 adults and adolescents living with HIV infection in the United States (MMWR, October, 2008). These new findings also indicate that African Americans and Hispanic/Latino populations continue to be disproportionately affected by HIV infection. Recent estimates showed that African Americans represented 46% and Hispanics/Latinos 18% of new HIV infections.

Individuals with substance use disorders are at increased risk for HIV/AIDS as a result of either sharing contaminated syringes or by exhibiting impaired judgment while under the influence of a legal or illegal drug with abuse potential (e.g., alcohol, cocaine, methamphetamine, marijuana, prescription, and/or other non-injection drugs) which may increase high risk sexual behavior associated with HIV infection and transmission.

Lastly, increasing rapid HIV testing efforts among SAMHSA MAI grantees will help to decrease the stigma associated with HIV by integrating HIV testing into routine best practices.

Supplemental grant funds must be used for the following activities:

- Purchase of rapid HIV test kits, test controls, other required supplies (e.g., gloves, biohazardous waste containers, etc.);
- Implementation of quality assurance measures to appropriately conduct rapid HIV testing; and
- Training for staff related to HIV rapid testing.

In addition to providing rapid HIV testing, applicants must develop a plan for providing referrals that include, but are not limited to: primary health care; and mental health and medical services for those who are HIV positive, have AIDS or are at high-risk of HIV infection.

You must also incorporate individuals served as a result of the supplemental activities into your ongoing Government Performance and Results Modernization Act of 2010 (GPRA) activities.

RHT Supplements are authorized under Section 509 of the Public Health Service Act, as amended. This announcement addresses Healthy People 2020 Substance Abuse Topic Area HP 2020-SA.

SAMHSA strongly encourages all grantees to provide a smoke-free workplace and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

II. AWARD INFORMATION

1. AWARD AMOUNT

It is expected that up to \$2.25 million will be available to fund up to 45 awards in FY 2011. Awards are expected to be up to \$50,000 in total costs (direct and indirect) for up to one year. Proposed budgets cannot exceed the allowable amount.

Applicants should be aware that SAMHSA cannot guarantee that sufficient funds will be appropriated to fully fund this program.

2. FUNDING MECHANISM

Awards will be made as grants.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

SAMHSA is limiting eligibility for this funding opportunity for the following cohorts of CSAT and CSAP MAI grantees:

- CSAT's FY 2007 Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services grantees;
- CSAP's FY 2008 and FY 2009 Prevention of Substance Abuse (SA) and HIV for At-Risk Racial/Ethnic Minority Subpopulations Cooperative Agreements grantees;
- CSAP's FY 2010 Substance Abuse and HIV Prevention Ready-To-Respond Initiative in Communities Highly Impacted by Substance Use and HIV Infection grantees; and
- CSAP's FY 2010 Capacity Building Initiative for Substance Abuse (SA) and HIV Prevention Services for At-Risk Racial/Ethnic Minority Young Adults grantees.

Limiting competition supports several of the activities outlined in the National HIV/AIDS Strategy – expanding HIV testing to reduce HIV incidence; increasing access to care by immediately linking newly diagnosed people to continuous and coordinated care; and allocating resources based on the latest epidemiological data about who is being most affected and other data that indicate which are the most urgent unmet needs to be addressed.

SAMHSA believes that the most effective way to accomplish the goals of this one-year supplemental program is to limit eligibility to the identified MAI grantees because they have the infrastructure already in place to rapidly implement the HIV rapid testing services without lengthy breaks in service and they do not have the funding to provide these services. MAI grantees whose funding period ends in FY 2010 are not eligible to apply because their projects will end before funding for these supplements will become available. MAI grantees whose funding period ends in FY 2011 are not eligible to apply because they will be phasing-out their current grants.

2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match are not required in this program.

3. OTHER

Additional Eligibility Requirements

You must use the HHS 5161-1 application package and comply with the formatting requirements in [Appendix A](#) of this document and certain program requirements, such as provisions relating to participant protection and the protection of human subjects specified in [Appendix F](#) of this document.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

Required application forms and guidelines are included in this mailing. You may download additional copies of the application forms from the SAMHSA Web site at <http://www.samhsa.gov/grants/apply.aspx>.

Additional materials available on this Web site include:

- a grant writing technical assistance manual for potential applicants;
- standard terms and conditions for SAMHSA grants;
- guidelines and policies that relate to SAMHSA grants (e.g., guidelines on cultural competence, consumer and family participation, and evaluation); and
- a list of certifications and assurances referenced in item 21 of the SF 424 v2.

2. CONTENT AND GRANT APPLICATION SUBMISSION

2.1 Application Kit

A complete list of documents included in the application kit is available at <http://www.samhsa.gov/Grants/ApplicationKit.aspx>. This includes:

- HHS 5161-1 (revised August 2007) – Includes the face page (SF 424 v2), budget forms, and checklist. You must use the HHS 5161-1.
- Cover Letter – Invites applications from eligible applicant(s).
- Request for Applications (RFA) – Includes instructions for the grant application. This document is the RFA.

You must use all of the above documents in completing your application.

2.2 Required Application Components

Applications should be complete and contain all information needed for review. In order for your application to be complete, it must include the following sections:

- **Face Page** – SF 424 v2 is the face page. This form is part of the HHS 5161-1. [Note: Applicants must provide a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. SAMHSA applicants are required to provide their DUNS number on the face page of the application. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access the Dun and Bradstreet Web site at <http://www.dunandbradstreet.com> or call 1-866-705-5711. To expedite the

process, let Dun and Bradstreet know that you are a public/private nonprofit organization getting ready to submit a Federal grant application. **You must use the same DUNS number for this submission that you used on your original application.** In addition, you must be registered in the Central Contractor (CCR) prior to submitting an application and maintain an active CCR registration during the grant funding period. **REMINDER: CCR registration expires each year and must be updated annually.** Additional information on the Central Contractor Registration (CCR) is available at <https://www.bpn.gov/ccr/default.aspx>].

- **Abstract** – Your total abstract must not be longer than 35 lines. 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, reporting to Congress, or press releases.
- **Table of Contents** – Include page numbers for each of the major sections of your application and for each attachment.
- **Budget Form** – Use SF 424A, which is part of the HHS 5161-1. Fill out Sections B, C, and E of the SF 424A. If you are requesting supplemental funding for one year, complete Section B only. A sample budget and justification is included in [Appendix E](#) of this document.
- **Project Narrative and Supporting Documentation** – The Project Narrative describes your project. It consists of Sections A through D. Sections A-D together may not be longer than 25 pages. (Remember that if your Project Narrative starts on page 5 and ends on page 30, it is 26 pages long, not 25 pages.) More detailed instructions for completing each section of the Project Narrative are provided in “Section V – Application Review Information” of this document.

The Supporting Documentation provides additional information necessary for the review of your application. This supporting documentation should be provided immediately following your Project Narrative in Sections E through G. There are no page limits for these sections, except for Section E, Biographical Sketches/Job Descriptions. Additional instructions for completing these sections are included in [Section V](#) under “Supporting Documentation.” Supporting documentation should be submitted in black and white (no color).

- **Attachments 1 through 3** – In your application, include the attachments below. Use only the attachments listed below. Please label the attachments as: Attachment 1, Attachment 2, etc.

- **Attachment 1:** 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 1.
- **Attachment 2:** Sample Consent Forms
- **Attachment 3:** Letter to the SSA (if applicable; see [Appendix C](#) of this document)
- **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.
- **Assurances** – Non-Construction Programs. You must read the list of assurances provided on the SAMHSA Web site and check the box marked ‘I Agree’ before signing the face page (SF 424 v2) of the application. You are also required to complete the Assurance of Compliance with SAMHSA Charitable Choice Statutes and Regulations Form SMA 170. This form will be posted on SAMHSA’s Web site with the RFA and provided in the application kit.
- **Certifications** – You must read the list of certifications provided on the SAMHSA Web site and check the box marked ‘I Agree’ before signing the face page (SF 424 v2) of the application.
- **Disclosure of Lobbying Activities** – You must submit Standard Form LLL found in the HHS 5161-1. 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 the Congress or State legislatures. This includes “grass roots” lobbying, which consists of appeals to members of the public suggesting that they contact their elected representatives to indicate their support for or opposition to pending legislation or to urge those representatives to vote in a particular way. If no lobbying is to be disclosed, mark N/A on the form. All applicants must sign the form.
- **Checklist** – Use the Checklist found in HHS 5161-1. The Checklist ensures that you have obtained the proper signatures, assurances and certifications. If you are submitting a paper application, the Checklist should be the last page.

2.3 Application Formatting Requirements

Applications must comply with basic application requirements. Failure to comply with these requirements may affect the ability of your application to be funded. See [Appendix A](#) of this document for a list of the specific formatting requirements and screenout criteria for SAMHSA grant applications.

3. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **June 1, 2011**. SAMHSA provides two options for submission of grant applications: 1) electronic submission, or 2) paper submission. Hard copy applications are due by **5:00 PM** (Eastern Time). Electronic applications are due by **11:59 PM** (Eastern Time). **Applications may be shipped using only Federal Express (FedEx), United Parcel Service (UPS), or the United States Postal Service (USPS)**. You will be notified by postal mail that your application has been received.

Note: If you use the USPS, you must use Express Mail.

SAMHSA will not accept or consider any applications that are hand carried or sent by facsimile.

Submission of Electronic Applications

If you plan to submit electronically through Grants.gov it is very important that you read thoroughly the application information provided in [Appendix B](#), "Guidance for Electronic Submission of Applications."

Submission of Paper Applications

If you are submitting a paper application, you must submit an original application and 2 copies (including attachments). The original and copies must not be bound and nothing should be attached, stapled, folded, or pasted. Do not use staples, paper clips, or fasteners. You may use rubber bands.

Send applications to the address below:

For United States Postal Service:

Crystal Saunders, Director of Grant Review
Office of Financial Resources
Substance Abuse and Mental Health Services Administration
Room 3-1044
1 Choke Cherry Road
Rockville, MD **20857**

Change the zip code to **20850** if you are using FedEx or UPS.

Do not send applications to other agency contacts, as this could delay receipt. Be sure to include “**RHT Supplements, TI-11-015**” in item number 12 on the face page (SF 424 v2) of any paper applications. If you require a phone number for delivery, you may use (240) 276-1199.

Failure to meet the timely submission requirements above may affect the ability of your application to be reviewed. Please remember that mail sent to Federal facilities undergoes a security screening prior to delivery. You are responsible for ensuring that you submit your application so that it will arrive by the application due date and time.

If an application is mailed to a location or office (including room number) that is not designated for receipt of the application and, as a result, the designated office does not receive your application by the deadline, it may affect the ability of your application to be reviewed.

SAMHSA accepts electronic submission of applications through <http://www.Grants.gov>. Please refer to [Appendix B](#) for “Guidance for Electronic Submission of Applications.”

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

This grant program is covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100. Under this Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. See [Appendix C](#) for additional information on these requirements as well as requirements for the Public Health Impact Statement.

5. FUNDING LIMITATIONS/RESTRICTIONS

Cost principles describing allowable and unallowable expenditures for Federal grantees, including SAMHSA grantees, are provided in the following documents, which are available at <http://www.samhsa.gov/grants/management.aspx>:

- Educational Institutions: 2 CFR Part 220 (OMB Circular A-21)
- State, Local and Indian Tribal Governments: 2 CFR Part 225 (OMB Circular A-87)
- Nonprofit Organizations: 2 CFR Part 230 (OMB Circular A-122)
- Hospitals: 45 CFR Part 74, Appendix E

SAMHSA grantees must also comply with SAMHSA’s standard funding restrictions, which are included in [Appendix D](#).

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

Your application will be reviewed and scored against the requirements listed below for developing the Project Narrative (Sections A-D). **These are to be used instead of the “Program Narrative” instructions found in the HHS 5161-1.** Independent reviewers will review and score your application and report to SAMHSA on the quality of your response to the requirements listed below, on issues that may impede the effective implementation of your project, and on participant protection issues that may need to be addressed. Deficiencies in your application may delay or prevent grant award or lead to special terms and conditions being placed on your award. In Sections A-D of the Project Narrative, you must clearly describe how you intend to use grant funds. Sections A-D of your application may not exceed 25 pages.

Section A: Progress to Date (20 points)

Describe your organization’s experience with the existing grant program. Report on accomplishments to date. Discuss any obstacles/problems that have been encountered and actions taken towards their resolution.

Section B: Proposed Approach for Program Expansion/Enhancement (30 points)

Describe your plans to expand or enhance your existing program and how your planned activities will meet the expected goals and objectives of the supplemental program. Clearly describe all activities that will be supported with the supplemental grant funds. Discuss how the supplemental activities will be integrated into the ongoing project. Describe roles and responsibilities of collaborating organizations, where applicable. Where applicable, provide the projected number of persons to be served, along with a clinical and demographic description of the projected number of persons to be served. Demonstrate how the proposed approach appropriately addresses factors such as age, race, ethnicity, culture, language, sexual orientation, disability, literacy and gender of the population. Provide the evidence base for any new services.

Clearly describe your plan for providing referrals that include, but are not limited to primary health care, and substance abuse, mental health and medical services for those who are HIV positive, have AIDS or are at high-risk of HIV infection.

Section C: Implementation Plan and Staffing (35 points)

Present your plan for implementing and managing the supplemental activities. Include a timeline for implementation showing key activities, milestones and responsible staff. Identify any cash or in-kind contributions that will be made to the project by the applicant or other partnering organizations.

Section D: Evaluation (15 points)

Describe how you will incorporate individuals served as a result of the supplemental activities into your ongoing Government Performance and Results Modernization Act of 2010 (GPRA) activities. Remember to include evaluation and data collection costs in your requested budget.

(Note: If there is other information about your proposed project that you deem important to the application, discuss it in the appropriate section(s) above, while staying within the 25 page limit.)

NOTE: Although the budget for the proposed project is not an evaluation criterion, the review group will be asked to comment on the appropriateness of the budget after the merits of the application have been considered.

SUPPORTING DOCUMENTATION

Section E: Job Descriptions and Biographical Sketches

- Include a biographical sketch for the Project Director and other key positions. Each sketch should be 2 pages or less. If the person has not been hired, include a position description and/or a letter of commitment with a current biographical sketch from the individual.
- Include job descriptions for key personnel. Job descriptions should be no longer than 1 page each.
- Information on what should be included in biographical sketches and job descriptions can be found on page 22, Item 6, in the Program Narrative section of the HHS 5161-1 instruction page, available on the SAMHSA Web site.

Section F: Budget Justification, Existing Resources, Other Support. You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Use SF 424, which is included in the HHS 5161-1. Fill out Sections B, C, and E. If you are requesting funding for one year, complete Section B only. An illustration of a budget and narrative justification is included in [Appendix E](#) of this document.

Section G: Confidentiality and SAMHSA Participant Protection/Human Subjects: You must describe procedures relating to Confidentiality, Participant Protection and the Protection of Human Subjects Regulations in Section G of your application. Problems with confidentiality, participant protection, and protection of human subjects identified during peer review of your application may result in the need to request additional information and may delay funding. See [Appendix F](#) for guidelines on these requirements.

2. REVIEW AND SELECTION PROCESS

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

Decisions to fund a grant are based on:

- the strengths and weaknesses of the application as identified by peer reviewers;
- availability of funds; and
- equitable distribution of awards in terms of geography (including urban, rural and remote settings) and balance among populations of focus and program size.

VI. ADMINISTRATION INFORMATION

1. AWARD NOTICES

You will receive a letter from SAMHSA through postal mail that describes the general results of the review of your application, including the score that your application received.

If you are approved for funding, you will receive an **additional** notice through postal mail, the Notice of Award (NoA), signed by SAMHSA's Grants Management Officer. The Notice of Award is the sole obligating document that allows you to receive Federal funding for work on the grant project.

2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

- If your application is funded, you must comply with all terms and conditions of the grant award. SAMHSA's standard terms and conditions are available on the SAMHSA Web site at <http://www.samhsa.gov/grants/management.aspx>.
- If your application is funded, you must also comply with the administrative requirements outlined in 45 CFR Part 74 or 45 CFR Part 92, as appropriate. For more information see the SAMHSA Web site (<http://www.samhsa.gov/grants/management.aspx>).
- Depending on the nature of the specific funding opportunity and/or your proposed project as identified during review, SAMHSA may negotiate additional terms and conditions with you prior to grant award. These may include, for example:
 - actions required to be in compliance with confidentiality and participant protection/human subjects requirements;

- requirements relating to additional data collection and reporting;
 - requirements relating to participation in a cross-site evaluation;
 - requirements to address problems identified in review of the application; or
 - revised budget and narrative justification.
- 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 of the grant award, or in reduction or withholding of continuation awards.
 - Grant funds cannot 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.
 - In an effort to improve access to funding opportunities for applicants, SAMHSA is participating in the U.S. Department of Health and Human Services “Survey on Ensuring Equal Opportunity for Applicants.” This survey is included in the application kit for SAMHSA grants and is posted on the SAMHSA Web site at <http://www.samhsa.gov/grants/downloads/SurveyEnsuringEqualOpp.pdf>. You are encouraged to complete the survey and return it, using the instructions provided on the survey form.

3. REPORTING REQUIREMENTS

3.1 Progress and Financial Reports

As a SAMHSA grantee, you will be required to submit progress and financial reports. The reports will be submitted at least annually and no more than quarterly (unless a high risk determination is made). The format and requirements for completing and submitting the reports will be provided to you by your Government Project Officer (GPO).

3.2 Publications

If you are funded under this grant program, you are required to notify the Government Project Officer (GPO) and SAMHSA’s Publications Clearance Officer (240-276-2130) of any materials based on the SAMHSA-funded grant project that are accepted for publication.

In addition, SAMHSA requests that grantees:

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

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

VII. AGENCY CONTACTS

For questions about program issues contact:

Sherrye C. McManus
Center for Substance Abuse Treatment, Division of Services Improvement
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 5-1065
(240) 276-2576
sherrye.mcmanus@samhsa.hhs.gov

For questions on grants management and budget issues contact:

Love Foster-Horton
Office of Financial Resources, Division of Grants Management
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 7-1095
Rockville, Maryland 20857
(240) 276-1653
love.foster-horton@samhsa.hhs.gov

Appendix A – Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications

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. **Failure to adhere to these requirements may affect the ability of your application to be funded.**

- Use the HHS 5161-1 application package.
- Applications must be received by the application due date and time, as detailed in [Section IV-3](#) of this grant announcement.
- Information provided must be sufficient for review.
- Text must be legible. Pages must be typed in black ink, single-spaced, using a font of Times New Roman 12, with all margins (left, right, top, bottom) at least one inch each. (For Project Narratives submitted electronically, see separate requirements in [Appendix B, “Guidance for Electronic Submission of Applications.”](#))
- To ensure equity among applications, page limits for the Project Narrative cannot be exceeded.
- Paper must be white paper and 8.5 inches by 11.0 inches in size.

To facilitate review of your application, follow these additional guidelines. The information provided in your application must be sufficient for review. Following these guidelines will help ensure your application is complete, and will help reviewers to consider your application.

- If you are submitting a paper application, the application components required for SAMHSA applications should be submitted in the following order:
 - Face Page (Standard Form 424 v2, which is in HHS 5161-1)
 - Abstract
 - Table of Contents
 - Budget Form (Standard Form 424A, which is in HHS 5161-1)
 - Project Narrative and Supporting Documentation
 - Attachments

- Project/Performance Site Location(s) Form
- Disclosure of Lobbying Activities (Standard Form LLL, which is in HHS 5161-1)
- Checklist (a form in HHS 5161-1)
- Applications should comply with the following requirements:
 - Provisions relating to confidentiality and participant protection specified in [Appendix F](#) of this announcement.
 - Budgetary limitations as specified in [Sections I, II](#), and [IV-5](#) of this announcement.
 - Documentation of nonprofit status as required in the HHS 5161-1.
- Black ink should be used throughout your application, including charts and graphs. Pages should be typed single-spaced with one column per page. Pages should not have printing on both sides.
- Pages should be numbered consecutively from beginning to end so that information can be located easily during review of the application. The abstract page should be page 1, the table of contents should be page 2, etc. The four pages of Standard form 424 v2 are not to be numbered. Attachments should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.
- The page limits for Attachments stated in Section IV-2.2 of this announcement should not be exceeded.
- Send the original application and two copies to the mailing address in [Section IV-3](#) of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. You may use rubber bands. Do not use heavy or lightweight paper or any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

Appendix B – Guidance for Electronic Submission of Applications

If you would like to submit your application electronically, you may search <http://www.Grants.gov> for the downloadable application package by the funding announcement number (called the opportunity number) or by the Catalogue of Federal Domestic Assistance (CFDA) number. You can find the CFDA number on the first page of the funding announcement.

You must follow the instructions in the User Guide available at the <http://www.Grants.gov> apply site, on the Help page. In addition to the User Guide, you may wish to use the following sources for technical (IT) help:

- By e-mail: support@Grants.gov
- By phone: 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.

If this is the first time you have submitted an application through Grants.gov, you must complete three separate registration processes before you can submit your application. Allow at least two weeks (10 business days) for these registration processes, prior to submitting your application. The processes are: 1) DUNS Number registration; 2) Central Contractor Registry (CCR) registration; and 3) Grants.gov registration (Get username and password.). **REMINDER: CCR registration expires each year and must be updated annually.** Be sure the person submitting your application is properly registered with Grants.gov as the Authorized Organization Representative (AOR) for the specific DUNS number cited on the SF 424 (face page). See the Organization Registration User Guide for details at the following Grants.gov link: http://www.grants.gov/applicants/get_registered.jsp.

Please also allow sufficient time for enter your application into Grants.gov. When you submit your application you will receive a notice that your application is being processed and that you will receive two e-mails from Grants.gov. within the next 24-48 hours. One will confirm receipt of the application in Grants.gov and the other will indicate that the application was either successfully validated by the system (with a tracking number) or rejected due to errors. It will also provide instructions that if you do not receive a receipt confirmation **and** a validation confirmation or a rejection e-mail within 48 hours, you must contact Grants.gov directly. Please note that it is incumbent on the applicant to monitor their application to ensure that it is successfully received and validated by Grants.gov. **If your application is not successfully validated by Grants.gov it will not be forwarded to SAMHSA as the receiving institution.**

It is strongly recommended that you prepare your Project Narrative and other attached documents using Microsoft Office 2003 products (e.g., Microsoft Word 2003, Microsoft Excel, etc.). The new Microsoft Vista operating system and Microsoft Word 2007 products are not currently accepted by Grants.gov. If you do not have access to Microsoft Office 2003 products, you may submit PDF files.

Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in your file being unreadable by our staff.

The Project Narrative must be a separate document in the electronic submission. Formatting requirements for SAMHSA grant applications are described in [Appendix A](#) of this announcement. These requirements also apply to applications submitted electronically, with the following exceptions only for Project Narratives submitted electronically in Microsoft Word. These requirements help ensure the accurate transmission and equitable treatment of applications.

- Text legibility: Use a font of Times New Roman 12, line spacing of single space, and all margins (left, right, top, bottom) of at least one inch each. Adhering to these standards will help to ensure the accurate transmission of your document.
- Amount of space allowed for Project Narrative: The Project Narrative for an electronic submission may not exceed **12,875** words. If the Project Narrative for an electronic submission exceeds the word limit, the application will be screened out and will not be reviewed. To determine the number of words in your Project Narrative document in Microsoft Word, select file/properties/statistics.

Keep the Project Narrative as a separate document. Please consolidate all other materials in your application to ensure the fewest possible number of attachments. Be sure to label each file according to its contents, e.g., “Attachments 1-3”, “Attachments 4-5.”

With the exception of standard forms in the application package, all pages in your application should be numbered consecutively. **Documents containing scanned images must also contain page numbers to continue the sequence.** Failure to comply with these requirements may affect the successful transmission and consideration of your application.

Applicants are strongly encouraged to submit their applications to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. It is important that you retain this number. **Receipt of the 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.**

Appendix C – Intergovernmental Review (E.O. 12373) Requirements

This grant program is covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100. Under this Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. Certain jurisdictions have elected to participate in the EO process and have established State Single Points of Contact (SPOCs). A current listing of SPOCs is included in the application kit and can be downloaded from the Office of Management and Budget (OMB) Web site at http://www.whitehouse.gov/omb/grants_spoc.

- Check the list to determine whether your State participates in this program. You do not need to do this if you are an American Indian/Alaska Native Tribe or tribal organization.
- If your State participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the State's review process.
- For proposed projects serving more than one State, you are advised to contact the SPOC of each affiliated State.
- The SPOC should send any State review process recommendations to the following address within 60 days of the application deadline. For United States Postal Service: Crystal Saunders, Director of Grant Review, Office of Financial Resources, Substance Abuse and Mental Health Services Administration, Room 3-1044, 1 Choke Cherry Road, Rockville, MD 20857. ATTN: SPOC – Funding Announcement No. **TI-11-015**. Change the zip code to 20850 if you are using another delivery service.

In addition, if you are a community-based, non-governmental service provider and you are not transmitting your application through the State, you must submit a Public Health System Impact Statement (PHSIS)¹ to the head(s) of appropriate State and local health agencies in the area(s) to be affected no later than the application deadline. The PHSIS is intended to keep State and local health officials informed of proposed health services grant applications submitted by community-based, non-governmental organizations within their jurisdictions. If you are a State or local government or American

¹ Approved by OMB under control no. 0920-0428; Public reporting burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the face page of SF 424 v2 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).

Indian/Alaska Native Tribe or tribal organization, you are not subject to these requirements.

The PHSIS consists of the following information:

- a copy of the face page of the application (SF 424 v2); and
- a summary of the project, no longer than one page in length, that provides: 1) a description of the population to be served; 2) a summary of the services to be provided; and 3) a description of the coordination planned with appropriate State or local health agencies.

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

If applicable, you must include a copy of a letter transmitting the PHSIS to the SSA in **Attachment 3, "Letter to the SSA."** The letter must notify the State that, if it wishes to comment on the proposal, its comments should be sent no later than 60 days after the application deadline to the following address. **For United States Postal Service:** Crystal Saunders, Director of Grant Review, Office of Financial Resources, Substance Abuse and Mental Health Services Administration, Room 3-1044, 1 Choke Cherry Road, Rockville, MD **20857**. ATTN: SSA – Funding Announcement No. **TI-11-015**. Change the zip code to **20850** if you are using another delivery service.

In addition:

- Applicants may request that the SSA send them a copy of any State comments.
- The applicant must notify the SSA within 30 days of receipt of an award.

Appendix D – Funding Restrictions

SAMHSA grant funds must be used for purposes supported by the program and may not be used to:

- Pay for any lease beyond the project period.
- Provide services to incarcerated populations (defined as those persons in jail, prison, detention facilities, or in custody where they are not free to move about in the community).
- Pay for the purchase or construction of any building or structure to house any part of the program. (Applicants may request up to \$75,000 for renovations and alterations of existing facilities, if necessary and appropriate to the project.)
- Provide residential or outpatient treatment services when the facility has not yet been acquired, sited, approved, and met all requirements for human habitation and services provision. (Expansion or enhancement of existing residential services is permissible.)
- Pay for housing other than residential mental health and/or substance abuse treatment.
- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.
- Make direct payments to individuals to induce them to enter prevention or treatment services. However, SAMHSA discretionary grant funds may be used for non-clinical support services (e.g., bus tokens, child care) designed to improve access to and retention in prevention and treatment programs.
- Make direct payments to individuals to encourage attendance and/or attainment of prevention or treatment goals. However, SAMHSA discretionary grant funds may be used for non-cash incentives of up to \$20 to encourage attendance and/or attainment of prevention or treatment goals when the incentives are built into the program design and when the incentives are the minimum amount that is deemed necessary to meet program goals. SAMHSA policy allows an individual participant to receive more than one incentive over the course of the program. However, non-cash incentives should be limited to the minimum number of times deemed necessary to achieve program outcomes. A grantee or treatment or prevention provider may also provide up to \$20 cash or equivalent (coupons, bus tokens, gifts, child care, and vouchers) to individuals as incentives to participate in required data collection follow up. This amount may be paid for participation in each required interview.

- Food is generally unallowable unless it's an integral part of a conference grant or program specific, e.g., children's program, residential.
- Award funds may not be used to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution.
- Pay for pharmacologies for HIV antiretroviral therapy, sexually transmitted diseases (STD)/sexually transmitted illnesses (STI), TB, and hepatitis B and C, or for psychotropic drugs.

SAMHSA will not accept a "research" indirect cost rate. The grantee must use the "other sponsored program rate" or the lowest rate available.

Appendix E – Sample Budget and Justification (no match required)

THIS IS AN ILLUSTRATION OF A SAMPLE DETAILED BUDGET AND NARRATIVE JUSTIFICATION WITH GUIDANCE FOR COMPLETING SF 424A: SECTION B FOR THE BUDGET PERIOD

A. Personnel: Provide employee(s) (including names for each identified position) of the applicant/recipient organization, including in-kind costs for those positions whose work is tied to the grant project.

FEDERAL REQUEST

Position	Name	Annual Salary/Rate	Level of Effort	Cost
(1) Project Director	John Doe	\$64,890	10%	\$6,489
(2) Grant Coordinator	To be selected	\$46,276	100%	\$46,276
(3) Clinical Director	Jane Doe	In-kind cost	20%	0
			TOTAL	\$52,765

JUSTIFICATION: Describe the role and responsibilities of each position.

- (1) The Project Director will provide daily oversight of the grant and will be considered key staff.
- (2) The Coordinator will coordinate project services and project activities, including training, communication and information dissemination.
- (3) The Clinical Director will provide necessary medical direction and guidance to staff for 540 clients served under this project.

Key staff positions require prior approval by SAMHSA after review of credentials of resume and job description.

FEDERAL REQUEST (enter in Section B column 1 line 6a of form SF424A) **\$52,765**

B. Fringe Benefits: List all components that make up the fringe benefits rate

FEDERAL REQUEST

Component	Rate	Wage	Cost
FICA	7.65%	\$52,765	\$4,037
Workers Compensation	2.5%	\$52,765	\$1,319
Insurance	10.5%	\$52,765	\$5,540
		TOTAL	\$10,896

JUSTIFICATION: Fringe reflects current rate for agency.

FEDERAL REQUEST (enter in Section B column 1 line 6b of form SF424A) **\$10,896**

C. Travel: Explain need for all travel other than that required by this application. Local travel policies prevail.

FEDERAL REQUEST

Purpose of Travel	Location	Item	Rate	Cost
(1) Grantee Conference	Washington, DC	Airfare	\$200/flight x 2 persons	\$400
		Hotel	\$180/night x 2 persons x 2 nights	\$720
		Per Diem (meals and incidentals)	\$46/day x 2 persons x 2 days	\$184
(2) Local travel		Mileage	3,000 miles @ .38/mile	\$1,140
			TOTAL	\$2,444

JUSTIFICATION: Describe the purpose of travel and how costs were determined.

(1) Two staff (Project Director and Evaluator) to attend mandatory grantee meeting in Washington, DC.

(2) Local travel is needed to attend local meetings, project activities, and training events. Local travel rate is based on organization's policies/procedures for privately owned vehicle reimbursement rate. If policy does not have a rate use GSA.

FEDERAL REQUEST (enter in Section B column 1 line 6c of form SF424A) **\$2,444**

D. Equipment: an article of tangible, nonexpendable, personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit (federal definition).

FEDERAL REQUEST – (enter in Section B column 1 line 6d of form SF424A) **\$ 0**

E. Supplies: materials costing less than \$5,000 per unit and often having one-time use

FEDERAL REQUEST

Item(s)	Rate	Cost
General office supplies	\$50/mo. x 12 mo.	\$600
Postage	\$37/mo. x 8 mo.	\$296
Laptop Computer	\$900	\$900
Printer	\$300	\$300
Projector	\$900	\$900
Copies	8000 copies x .10/copy	\$800
	TOTAL	\$3,796

JUSTIFICATION: Describe the need and include an adequate justification of how each cost was estimated.

(1) Office supplies, copies and postage are needed for general operation of the project.

(2) The laptop computer and printer are needed for both project work and presentations for Project Director.

(3) The projector is needed for presentations and workshops. All costs were based on retail values at the time the application was written.

FEDERAL REQUEST – (enter in Section B column 1 line 6e of form SF424A) \$ 3,796

F. Contract: A contractual arrangement to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may be in the form of consortium agreements or contracts. A consultant is an individual retained to provide professional advice or services for a fee. The applicant/grantee must establish written procurement policies and procedures that are consistently applied. All procurement transactions shall be conducted in a manner to provide to the maximum extent practical, open and free competition.

COSTS FOR CONTRACTS MUST BE BROKEN DOWN IN DETAIL AND A NARRATIVE JUSTIFICATION PROVIDED. IF APPLICABLE, NUMBERS OF CLIENTS SHOULD BE INCLUDED IN THE COSTS.

FEDERAL REQUEST

Name	Service	Rate	Other	Cost
(1) State Department of Human Services	Training	\$250/individual x 3 staff	5 days	\$750
(2) Treatment Services	1040 Clients	\$27/client per year		\$28,080

Name	Service	Rate	Other	Cost
(3) John Smith (Case Manager)	Treatment Client Services	1FTE @ \$27,000 + Fringe Benefits of \$6,750 = \$33,750	*Travel at 3,124 @ .50 per mile = \$1,562 *Training course \$175 *Supplies @ \$47.54 x 12 months or \$570 *Telephone @ \$60 x 12 months = \$720 *Indirect costs = \$9,390 (negotiated with contractor)	\$46,167
(4) Jane Smith	Evaluator	\$40 per hour x 225 hours	12 month period	\$9,000
(5) To Be Announced	Marketing Coordinator	Annual salary of \$30,000 x 10% level of effort		\$3,000
			TOTAL	\$86,997

JUSTIFICATION: Explain the need for each contractual agreement and how it relates to the overall project.

- (1) Certified trainers are necessary to carry out the purpose of the Statewide Consumer Network by providing recovery and wellness training, preparing consumer leaders statewide, and educating the public on mental health recovery.
- (2) Treatment services for clients to be served based on organizational history of expenses.

- (3) Case manager is vital to client services related to the program and outcomes.
- (4) Evaluator is provided by an experienced individual (Ph.D. level) with expertise in substance abuse, research and evaluation, is knowledgeable about the population of focus, and will report GPRA data.
- (5) Marketing Coordinator will develop a plan to include public education and outreach efforts to engage clients of the community about grantee activities, and provision of presentations at public meetings and community events to stakeholders, community civic organizations, churches, agencies, family groups and schools.

***Represents separate/distinct requested funds by cost category**

FEDERAL REQUEST – (enter in Section B column 1 line 6f of form SF424A) **\$86,997**

G. Construction: NOT ALLOWED – Leave Section B columns 1& 2 line 6g on SF424A blank.

H. Other: expenses not covered in any of the previous budget categories

FEDERAL REQUEST

Item	Rate	Cost
(1) Rent*	\$15/sq.ft x 700 sq. feet	\$10,500
(2) Telephone	\$100/mo. x 12 mo.	\$1,200
(3) Client Incentives	\$10/client follow up x 278 clients	\$2,780
(4) Brochures	.89/brochure X 1500 brochures	\$1,335
	TOTAL	\$15,815

JUSTIFICATION: Break down costs into cost/unit (e.g. cost/square foot). Explain the use of each item requested.

(1) Office space is included in the indirect cost rate agreement; however, if other rental costs for service site(s) are necessary for the project, they may be requested as a direct charge. The rent is calculated by square footage or FTE and reflects SAMHSA’s fair share of the space.

***If rent is requested (direct or indirect), provide the name of the owner(s) of the space/facility. If anyone related to the project owns the building which is less than an arms length arrangement, provide cost of ownership/use allowance calculations. Additionally, the lease and floor plan (including common areas) is required for all projects allocating rent costs.**

(2) The monthly telephone costs reflect the % of effort for the personnel listed in this application for the SAMHSA project only.

(3) The \$10 incentive is provided to encourage attendance to meet program goals for 278 client follow-ups.

(4) Brochures will be used at various community functions (health fairs and exhibits).

FEDERAL REQUEST – (enter in Section B column 1 line 6h of form SF424A) \$15,815

Indirect Cost Rate: Indirect costs can be claimed if your organization has a negotiated indirect cost rate agreement. It is applied only to direct costs to the agency as allowed in the agreement. For information on applying for the indirect rate go to:

<http://www.samhsa.gov> then click on Grants – Grants Management – Contact Information – Important Offices **at SAMHSA and DHHS - HHS Division of Cost Allocation – Regional Offices.**

FEDERAL REQUEST (enter in Section B column 1 line 6j of form SF424A)

8% of personnel and fringe (.08 x \$63,661) \$5,093

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TOTAL DIRECT CHARGES:

**FEDERAL REQUEST – (enter in Section B column 1 line 6i of form SF424A)
\$172,713**

INDIRECT CHARGES:

**FEDERAL REQUEST – (enter in Section B column 1 line 6j of form SF424A)
\$5,093**

TOTALS: (sum of 6i and 6j)

FEDERAL REQUEST – (enter in Section B column 1 line 6k of form SF424A) \$177,806

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UNDER THIS SECTION REFLECT OTHER NON-FEDERAL SOURCES OF FUNDING BY DOLLAR AMOUNT AND NAME OF FUNDER e.g., Applicant, State, Local, Other, Program Income, etc.

Provide the total proposed Project Period and Federal funding as follows:

Proposed Project Period

a. Start Date:	09/30/2011	b. End Date:	09/29/2016
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BUDGET SUMMARY (should include future years and projected total)

Category	Year 1	Year 2*	Year 3*	Year 4*	Year 5*	Total Project Costs
Personnel	\$52,765	\$54,348	\$55,978	\$57,658	\$59,387	\$280,136
Fringe	\$10,896	\$11,223	\$11,559	\$11,906	\$12,263	\$57,847
Travel	\$2,444	\$2,444	\$2,444	\$2,444	\$2,444	\$12,220
Equipment	0	0	0	0	0	0
Supplies	\$3,796	\$3,796	\$3,796	\$3,796	\$3,796	\$18,980
Contractual	\$86,997	\$86,997	\$86,997	\$86,997	\$86,997	\$434,985
Other	\$15,815	\$13,752	\$11,629	\$9,440	\$7,187	\$57,823
Total Direct Charges	\$172,713	\$172,560	\$172,403	\$172,241	\$172,074	\$861,991
Indirect Charges	\$5,093	\$5,246	\$5,403	\$5,565	\$5,732	\$27,039
Total Project Costs	\$177,806	\$177,806	\$177,806	\$177,806	\$177,806	\$889,030

TOTAL PROJECT COSTS: Sum of Total Direct Costs and Indirect Costs

FEDERAL REQUEST (enter in Section B column 1 line 6k of form SF424A) **\$889,030**

***FOR REQUESTED FUTURE YEARS:**

1. Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.

2. If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policy and procedures that state all employees within the organization will receive a COLA.

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

Confidentiality and Participant Protection:

Because of the confidential nature of the work in which many SAMHSA grantees are involved, it is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. All applicants must address the seven elements below. If some are not applicable or relevant to the proposed project, simply state that they are not applicable and indicate why. In addition to addressing these seven elements, read the section that follows entitled Protection of Human Subjects Regulations to determine if the regulations may apply to your project. If so, you are required to describe the process you will follow for obtaining Institutional Review Board (IRB) approval. While we encourage you to keep your responses brief, there are no page limits for this section and no points will be assigned by the Review Committee. Problems with confidentiality, participant protection, and the protection of human subjects identified during peer review of the application must be resolved prior to funding.

1. Protect Clients and Staff from Potential Risks

- Identify and describe any foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects as a result of the project itself or any data collection activity.
- Describe the procedures you will follow to minimize or protect participants against potential risks, including risks to confidentiality.
- Identify plans to provide guidance and assistance in the event there are adverse effects to participants.
- Where appropriate, describe alternative treatments and procedures that may be beneficial to the participants. If you choose not to use these other beneficial treatments, provide the reasons for not using them.

2. Fair Selection of Participants

- Describe the population(s) of focus for the proposed project. Include age, gender, and racial/ethnic background and note if the population includes homeless youth, foster children, children of substance abusers, pregnant women, or other targeted groups.
- Explain the reasons for including groups of pregnant women, children, people with mental disabilities, people in institutions, prisoners, and individuals who are likely to be particularly vulnerable to HIV/AIDS.
- Explain the reasons for including or excluding participants.

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

3. Absence of Coercion

- Explain if participation in the project is voluntary or required. Identify possible reasons why participation is required, for example, court orders requiring people to participate in a program.
- If you plan to compensate participants, state how participants will be awarded incentives (e.g., money, gifts, etc.). Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an “undue inducement” which removes the voluntary nature of participation. Incentives should be the minimum amount necessary to meet the programmatic and performance assessment goals of the grant. Applicants should determine the minimum amount that is proven effective by consulting with existing local programs and reviewing the relevant literature. In no case may the value of an incentive paid for with SAMHSA discretionary grant funds exceed \$20.
- State how volunteer participants will be told that they may receive services intervention even if they do not participate in or complete the data collection component of the project.

4. Data Collection

- Identify from whom you will collect data (e.g., from participants themselves, 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). Where data are to be collected through observational techniques, questionnaires, interviews, or other direct means, describe the data collection setting.
- Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation or if other use(s) will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.
- Provide in **Attachment 1, “Data Collection Instruments/Interview Protocols,”** copies of all available data collection instruments and interview protocols that you plan to use.

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.

- Describe:
 - How you will use data collection instruments.
 - Where data will be stored.
 - Who will or will not have access to information.
 - How the identity of participants will be kept private, for example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

NOTE: If applicable, grantees must agree to 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.**

6. Adequate Consent Procedures

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Identify the data that will be collected, how the data will be used and how you will keep the data private.
- State:
 - Whether or not their participation is voluntary.
 - Their right to leave the project at any time without problems.
 - Possible risks from participation in the project.
 - Plans to protect clients from these risks.
- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

NOTE: If the project poses potential physical, medical, psychological, legal, social or other risks, you **must** obtain written informed consent.

- Indicate if you will obtain informed consent from participants or assent from minors along with consent from their parents or legal guardians. 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?
- 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 2, “Sample Consent Forms”**, of your application. If needed, give English translations.

NOTE: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both participant protection in treatment intervention and for the collection and use of data?
- Additionally, if other consents (e.g., consents to release information to others or gather information from others) will be used in your project, provide a description of the consents. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

7. Risk/Benefit Discussion

- Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

Protection of Human Subjects Regulations

SAMHSA expects that most grantees 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 performance assessment design may meet the regulation’s criteria for research involving human subjects. For assistance in determining if your proposed performance assessment meets the criteria in 45 CFR 46, Protection of Human Subjects Regulations, refer to the SAMHSA decision tree on the SAMHSA Web site, under “Applying for a New SAMHSA Grant,” <http://www.samhsa.gov/grants/apply.aspx>.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must fully describe the process for obtaining IRB approval. While IRB approval is not required at the time of grant award, these grantees will be required, as a condition of award, to provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP). IRB approval must be received in these cases prior to enrolling participants in the project. General information about Human Subjects Regulations can be obtained through OHRP at <http://www.hhs.gov/ohrp>, or ohrp@osophs.dhhs.gov, or (240) 453-6900. SAMHSA–specific questions should be directed to the program contact listed in [Section VII](#) of this announcement.