

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Opioid Treatment Program Accreditation Grants
Short Title: Accreditation of OTPs

(Initial Announcement)

Request for Applications (RFA) No. TI-08-008

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

Key Dates:

Application Deadline	Applications are due by January 8, 2008
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Executive Summary:

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (CSAT) is accepting applications for fiscal year (FY) 2008 for Opioid Treatment Program (OTP) Accreditation grants. The purpose of this program is to reduce the costs of basic accreditation education and accreditation/reaccreditation surveys (site visits) for OTPs participating in the accreditation process pursuant to Title 42 of the Code of Federal Regulations Part 8 (42 CFR Part 8). A copy of 42 CFR Part 8 is available at <http://www.dpt.samhsa.gov/pdf/regs.pdf>. CSAT is announcing the OTP Accreditation Program for a final cycle of 3 years.

Funding Opportunity Title:	OTP Accreditation Grants
Funding Opportunity Number:	TI-08-008
Due Date for Applications:	January 8, 2008
Anticipated Total Available Funding:	\$1 million
Estimated Number of Awards:	6
Estimated Award Amount:	\$7,500-\$500,000
Length of Project Period:	Up to 3 years
Eligible Applicants:	Eligibility is limited to SAMHSA-approved accreditation bodies: CARF, the Rehabilitation Accreditation Commission; the Council on Accreditation; the Joint Commission on Accreditation of Healthcare Organizations; the Division of Alcohol and Substance Abuse, Washington Department of Social and Health Services; the Division of Alcohol and Drug Abuse, State of Missouri; and the National Commission on Correctional Health Care.

I. FUNDING OPPORTUNITY DESCRIPTION

1. INTRODUCTION

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (CSAT) is accepting applications for fiscal year (FY) 2008 for Opioid Treatment Program (OTP) Accreditation grants. The purpose of this program is to reduce the costs of basic accreditation education and accreditation/reaccreditation surveys (site visits) for OTPs participating in the accreditation process pursuant to Title 42 of the Code of Federal Regulations Part 8 (42 CFR Part 8). A copy of 42 CFR Part 8 is available at <http://www.dpt.samhsa.gov/pdf/regs.pdf>. CSAT is announcing the OTP Accreditation Program for a final cycle of 3 years.

This grant program was introduced to assist OTPs in transitioning to the new accreditation process. It was important for SAMHSA to assist in the transition to accreditation to ensure continuity of OTP operations and prevent instability in the provision of treatment services, to improve the quality of treatment in opioid treatment programs and to ensure that OTPs meet minimum standards of care. The current OTP Accreditation Grant Program, which expires March 2008, has provided funding for six grantees to conduct a second round of accreditation surveys for approximately 1167 OTPs.

The OTP Accreditation Grant Program was never intended to become permanent. Now that the vast majority of the OTPs have been reaccredited, CSAT believes it is time to phase out the program.

During this cycle, the support available to defray the costs of basic accreditation education and accreditation surveys will be reduced by about 50 percent from the level available under previous cycles of the program. This final grant cycle will allow OTPs to prepare to assume the full costs of accreditation after the program ends.

2. EXPECTATIONS

OTPs are required to attain accreditation as a part of the process of SAMHSA certification. Certification is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. In order to maintain a full and current certification from SAMHSA, an OTP must:

- Meet Federal opioid treatment standards found in 42 CFR Part 8.12;
- Have been awarded an initial accreditation and subsequent reaccreditations (at least every 3 years) by a SAMHSA-approved accreditation body; and
- Comply with any other conditions for certification established by SAMHSA.

Grantees will be SAMHSA-approved accreditation bodies and will be expected to:

- Prepare OTPs for accreditation through education;

- Conduct accreditation/reaccreditation surveys using a peer review process;
- Report accreditation/reaccreditation survey findings to OTPs and to SAMHSA. Use these survey findings for constructive feedback to OTPs;
- Follow-up to ensure corrective action has been taken to optimize program functioning and treatment processes and to improve patient outcomes for the targeted population, that is, persons addicted to opiates;
- Conduct "for cause" surveys of OTPs at the request of SAMHSA. "For cause" surveys are required to follow up on allegations of regulatory noncompliance or a pattern of complaints about an OTP.

A copy of the updated CSAT Guidelines for the Accreditation of Opioid Treatment Programs can be downloaded from <http://dpt.samhsa.gov/pdf/OTPAccredGuidelines-2007.pdf>.

Goals for this program include maintaining accreditation in over 1100 OTPs nationwide. Accreditation provides OTPs with the opportunity to establish or improve methods of continuous quality improvement and to underscore best practices in the field of opioid treatment. In addition, accreditation is focused on improving OTP administration and management, which presently varies widely. Other goals include increasing staff retention; providing significantly more opportunities for OTP staff training; making comprehensive services more available; making emergency services more available; increasing patient access to treatment, and improving positive patient outcomes. Being approved by a nationally recognized accreditation organization will give increased credibility to programs, remove some of the stigma frequently associated with this treatment modality, and make OTPs a part of the mainstream health care system.

2.1 Data Collection and Performance Measurement

All SAMHSA grantees are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). This information will be gathered using the data collection tool referenced below.

You must document your ability to collect and report the required data in "Section D: Performance Assessment and Data" of your application. Grantees must collect and report data using the **CSAT Training Baseline and Follow-up GPRA forms**, which can be found at www.samhsa-gpra.samhsa.gov, along with instructions for completing it. Hard copies are available by calling the SAMHSA Information Line at 1-877-SAMHSA7 [TDD: 1-800-487-4889].

The following GPRA measures have been established for this program:

- Number of OTPs that have submitted applications for surveys;
- Number of OTPs receiving accreditation surveys/site visits with assistance from this grant;
- Results of each OTP accreditation survey supported by this grant; and
- Percentage of OTP sponsors or directors satisfied with the accreditation process.

(Note: This information on satisfaction with the accreditation process will be collected from ongoing assessments developed and conducted independently by grantee organizations as a usual and customary part of the accreditation process.)

In addition to these measures, grantees will be expected to collect and report GPRA baseline (end of event) data and 30-day follow-up to the event (with a minimum 80% of all baseline participants followed up) on all participants at training events. Data are to be collected using the CSAT Training Baseline and Follow-up GPRA forms and submitted using the Web-based CSAT GPRA data collection system (SAIS) within 7 days after data is collected.

Training and technical assistance on data collecting, tracking and follow-up as well as data entry, will be provided by CSAT.

GPRA data will be reported to the public, the Office of Management and Budget (OMB) and Congress as part of SAMHSA's budget request.

The terms and conditions of the grant award also will specify the data to be submitted and the schedule for submission. Grantees will be required to adhere to these terms and conditions of award.

2.2 Performance Assessment

Grantees must assess their projects, addressing the performance measures described in Section I-2.1. The 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. You will be required to report on your progress achieved, barriers encountered, and efforts to overcome these barriers in a performance assessment report to be submitted at least annually.

In addition to assessing progress against the performance measures required for this program, your performance assessment must also consider outcome and process questions, such as the following:

Outcome Questions:

- What was the effect of intervention on participants?
- What program/contextual factors were associated with outcomes?
- What individual factors were associated with outcomes?
- How durable were the effects?

Process Questions:

- How closely did implementation match the plan?
- What types of deviation from the plan occurred?
- What led to the deviations?
- What effect did the deviations have on the planned intervention and performance assessment?

- Who provided (program staff) what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

No more than 5% of the total grant award may be used for data collection, performance measurement, and performance assessment, e.g., activities required in Sections I-2.1 and 2.2 above.

2.3 Grantee Meetings

Your Project Director must plan to participate in two joint grantee meetings per year, and you must include funding for this travel in your budget. At these meetings, grantees will present the results of their projects and Federal staff will provide technical assistance. Each meeting will be up to two days, and attendance is mandatory. One meeting will usually be held in the Washington, D.C., area. The second meeting will be held in connection with another appropriate national meeting such as the American Association for Treatment of Opioid Dependence Conference.

II. AWARD INFORMATION

1. AWARD AMOUNT

Funding Mechanism:	Grant
Anticipated Total Available Funding:	\$1,000,000
Estimated Number of Awards:	Up to 6
Estimated Award Amount:	\$7,500 to \$500,000 per year
Length of Project Period:	Up to 3 years

The amount of an individual award is expected to range between \$7,500 and \$500,000 in total costs (direct and indirect) in any year of the proposed project. The maximum allowable annual award is \$500,000 in total costs. The amount of an award will be determined by an estimate of the number of OTPs the grantee is expected to accredit/reaccredit. For example, SAMHSA-approved accreditation bodies that are State organizations will accredit only OTPs in their State. These currently total less than 20 OTPs. Other accrediting body applicants will estimate the number of OTPs already planned for or expected to apply for accreditation or reaccreditation in their grant applications. During each triennial accreditation cycle, OTPs are permitted to change accreditation bodies in some circumstances. Award amounts will be determined based on the information provided in the application and an equitable distribution will be determined during the award decision-making process.

When preparing your budget, you must adhere to the following guidelines/limitations:

- Basic OTP accreditation and reaccreditation education is limited to \$500 or less per OTP.
- The actual cost of conducting site visits for accreditation, reaccreditation, monitoring purposes or "for-cause" visits is limited to \$2,000 or less per site visit.

Proposed budgets cannot exceed the allowable amount in any year of the proposed project. Annual continuation awards will depend on the availability of funds, grantee progress in meeting program goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award.

This program is being announced prior to the annual appropriation for FY 2008 for SAMHSA's programs, with funding estimates based on the President's budget request for FY 2008. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2008 to permit funding of a reasonable number of applications hereby solicited. All applicants are reminded, however, that we cannot guarantee that sufficient funds will be appropriated to permit SAMHSA to fund any applications.

2. FUNDING MECHANISM

Awards for this funding opportunity will be made as grants.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Only SAMHSA approved accreditation bodies are eligible applicants. This is because under Federal regulation, "The Final Rule on Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction" (42 CFR Part 8), private nonprofit organizations or State governmental agencies, or political subdivisions thereof, must be approved by SAMHSA in order to conduct accreditation processes and site visits with OTPs. Therefore, grant applications from organizations that have not met the regulatory requirements, i.e., have not been approved by SAMHSA as an accreditation body, will not be considered for an award. At present, the only six eligible applicants are the following SAMHSA-approved accreditation bodies: CARF, The Rehabilitation Accreditation Commission; the Council on Accreditation; the Joint Commission on Accreditation of Healthcare Organizations; the Division of Alcohol and Substance Abuse, Washington Department of Social and Health Services; the Division of Alcohol and Drug Abuse, State of Missouri; and the National Commission on Correctional Health Care.

2. COST SHARING and MATCH REQUIREMENTS

Cost sharing/match are not required in this program.

3. OTHER

You must comply with the following requirements, or your application will be screened out and will not be reviewed: use of the PHS 5161-1 application form; application submission

requirements in Section IV-3 of this document; and formatting requirements provided in Appendix A of this document.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

You may request a complete application kit from the SAMHSA Information Line at 1-877-SAMHSA7 [TDD: 1-800-487-4889].

You also may download the required documents from the SAMHSA Web site at 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 FORM OF APPLICATION SUBMISSION

2.1 Application Kit

SAMHSA application kits include the following documents:

- PHS 5161-1 (revised July 2000) – Includes the face page (SF 424 v2), budget forms, assurances, certification, and checklist. You must use the PHS 5161-1. **Applications that are not submitted on the required application form will be screened out and will not be reviewed.**
- Request for Applications (RFA) – Provides a description of the program, specific information about the availability of funds, and instructions for completing the grant application. This document is the RFA. The RFA will be available on the SAMHSA Web site (www.samhsa.gov/grants/index.aspx) and a synopsis of the RFA is available on the Federal grants Web site (www.Grants.gov).

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

2.2 Required Application Components

Applications must include the required ten application components (Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist).

- ❑ **Face Page** – SF 424 v2 is the face page. This form is part of the PHS 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 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.]
- ❑ **Abstract** – Your total abstract should not be longer than 35 lines. It should include the project name, population 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 appendix.
- ❑ **Budget Form** – Use SF 424A, which is part of the PHS 5161-1. Fill out Sections B, C, and E of the SF 424A. 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 30 pages. (Remember that if your Project Narrative starts on page 5 and ends on page 35, it is 31 pages long, not 30 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 G, 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).

- ❑ **Appendices 1 through 3** – Use only the appendices listed below. If your application includes any appendices not required in this document, they will be disregarded. Do not use more than a total of 30 pages for Appendices 1 and 2 combined. There is no page limitation for Appendix 3. Do not use appendices to extend or replace any of the sections of the Project Narrative. Reviewers will not consider them if you do.
 - *Appendix 1: Data Collection Instruments/Interview Protocols*
 - *Appendix 2: Sample Consent Forms*

- *Appendix 3: Copy of your Accreditation Standards Manual, including OTP standards*
- ❑ **Assurances** – Non-Construction Programs. You must read the list of assurances provided on the SAMHSA Web site or in the application kit before signing the face page (SF 424 v2) of the application.
- ❑ **Certifications** – You must read the list of certifications provided on the SAMHSA Web site or in the application kit before signing the face page (SF 424 v2) of the application.
- ❑ **Disclosure of Lobbying Activities** – You must submit Standard Form LLL found in the PHS 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.
- ❑ **Checklist** – Use the Checklist found in PHS 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

Please refer to Appendix A, *Checklist for Formatting Requirements and Screenout Criteria for SAMHSA Grant Applications*, for SAMHSA’s basic application formatting requirements. Applications that do not comply with these requirements will be screened out and will not be reviewed.

3. SUBMISSION DATES AND TIMES

Applications are due by close of business on **January 8, 2008**. Hard copy applications are due by 5:00 PM (EST). Electronic applications are due by 12:00 midnight (EST). **Hand carried applications will not be accepted. Applications may be shipped using only DHL, 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.

Your application must be received by the application deadline or it will not be considered for review. 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, your application will be considered late and ineligible for review.

SAMHSA will not accept or consider any applications sent by facsimile.

SAMHSA accepts electronic submission of applications through www.Grants.gov. Please refer to Appendix B for “Guidance for Electronic Submission of Applications.”

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

The purpose of the “Accreditation of OTPs” program is to partially subsidize the cost of the accreditation of opioid treatment programs. Grants are intended to reduce the costs of basic accreditation education and accreditation/reaccreditation surveys (site visits) for OTPs participating in the accreditation process pursuant to Title 42 of the Code of Federal Regulations Part 8 (42 CFR Part 8). None of the six eligible applicants (i.e., SAMHSA-approved Accreditation bodies pursuant to 42 CFR Part 8) will be providing direct substance abuse treatment services and four of the six will be performing accreditation surveys at opioid treatment programs throughout the U.S. Therefore, the Public Health System Impact Statement (PHSIS) reporting requirements are not applicable. The Intergovernmental Review (E.O. 12372) requirement for applicants serving more than one State to contact the Single Point of Contact of each affiliated State would be an overly burdensome reporting requirement for the four eligible entities serving OTPs in multiple States, and is, therefore, not required for the “Accreditation of OTPs” program.

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 www.samhsa.gov/grants/management.aspx:

- Institutions of Higher Education: OMB Circular A-21
- State and Local Governments and Federally Recognized Indian Tribal Governments: OMB Circular A-87
- Nonprofit Organizations: OMB Circular A-122
- Hospitals: 45 CFR Part 74, Appendix E

In addition, SAMHSA Grant recipients must comply with the following funding restrictions:

- Grant funds must not be used for any purposes except accreditation/reaccreditation education, the accreditation/reaccreditation surveys or “for cause” surveys at the request of SAMHSA.
- Grant funds may not be used to subsidize the accreditation survey process for OTPs operated by the Department of Veterans Affairs or by other Federal agencies.
- No more than 5% of the grant award may be used for evaluation and data collection expenses.

- Grant funds may not be used to pay for the purchase or construction of any building or structure to house any part of the grant project.

SAMHSA grantees must also comply with SAMHSA’s standard funding restrictions, which are included in Appendix D.

6. OTHER SUBMISSION REQUIREMENTS

You may submit your application in either electronic or paper format:

Submission of Electronic Applications

SAMHSA accepts electronic submission of applications through www.Grants.gov. Electronic submission is voluntary. No review points will be added or deducted, regardless of whether you use the electronic or paper format.

To submit an application electronically, you must use the www.Grants.gov apply site. You will be able to download a copy of the application package from www.Grants.gov, complete it off-line, and then upload and submit the application via the Grants.gov site. E-mail submissions will not be accepted.

Please refer to Appendix B for detailed instructions on submitting your application electronically.

Submission of Paper Applications

You must submit an original application and 2 copies (including appendices). The original and copies must not be bound. Do not use staples, paper clips, or fasteners. Nothing should be attached, stapled, folded, or pasted.

Send applications to the address below:

For United States Postal Service:

Crystal Saunders, Director of Grant Review
Office of Program Services
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 another delivery service.

Do not send applications to other agency contacts, as this could delay receipt. Be sure to include “**Accreditation of OTPs – TI-08-008**” 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.

Hand carried applications will not be accepted. Applications may be shipped using only DHL, Federal Express (FedEx), United Parcel Service (UPS), or the United States Postal Service (USPS).

SAMHSA will not accept or consider any applications sent by facsimile.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

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

- In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program. **These are to be used instead of the “Program Narrative” instructions found in the PHS 5161-1.**
- The Project Narrative (Sections A-D) together may be no longer than 30 pages.
- You must use the four sections/headings listed below in developing your Project Narrative. Be sure to place the required information in the correct section, **or it will not be considered.** Your application will be scored according to how well you address the requirements for each section of the Project Narrative.
- Reviewers will be looking for evidence of cultural competence in each section of the Project Narrative, and will consider how well you address the cultural competence aspects of the evaluation criteria when scoring your application. SAMHSA’s guidelines for cultural competence can be found on the SAMHSA Web site at www.samhsa.gov. Click on “Grants/Applying for a New SAMHSA Grant/Guidelines for Assessing Cultural Competence.”
- The Supporting Documentation you provide in Sections E-G and Appendices 1-3 will be considered by reviewers in assessing your response, along with the material in the Project Narrative.
- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual bullets, applicants are encouraged to respond to each bulleted statement.

Section A: Project Description: (20 points)

- List your project goals and objectives and describe how they relate to the purpose and goals of this RFA. In particular, describe your goals for the provision of accreditation/reaccreditation education and the accreditation/reaccreditation surveys. For

example, to whom will you provide the accreditation/reaccreditation education and what will be the intended outcomes of that education? How will reaccreditation training differ from accreditation training? How many accreditation/reaccreditation surveys do you anticipate conducting during the 3-year project period? What is your time frame for initiating and completing the anticipated accreditation/reaccreditation surveys?

- Discuss the functions and roles that your proposed project will require your organization to develop and your approach to the challenges and obstacles involved in these efforts.
- Discuss your experience to date doing accreditation/reaccreditation surveys and education including problems and their resolutions as well as lessons learned.
- Provide an estimate of the usual, average charges billed for an accreditation/reaccreditation survey of an OTP, and the incremental increase for accreditation as an OTP when part of a broader accreditation survey. Identify any cash and in-kind contributions that will be made to the project.

Section B: Proposed Approach (35 points)

- Describe the processes, activities, methodologies, and approaches that will achieve project goals and objectives.
- Describe the OTP educational activities to be conducted to prepare OTPs for accreditation and reaccreditation.
- Describe how required activities and reporting requirements will be carried out.
- Describe examples of problems that may occur and strategies for overcoming them. SAMHSA is particularly interested in learning about your organization's strategies for educating and preparing for accreditation those OTPs which have severe quality problems or which are particularly resistant to adhering to accreditation standards.
- Describe how the accreditation body will use approaches that are culturally appropriate and competent in addressing age, culture, race/ethnicity, language, sexual orientation, gender, and disability issues.

Section C: Staff, Management, and Relevant Experience (30 points)

- Describe the project director's experience and qualifications in the fields of opioid treatment, continuous quality improvement, and accreditation.
- Describe the specific expertise of key personnel in medication-assisted treatment and in the development of accreditation standards.

- Describe the experience of key personnel in management, administration, accreditation technical assistance, meeting planning, and automated data processing, which make them qualified to carry out project tasks.
- Justify proposed time commitments of key personnel.
- Describe the feasibility of accomplishing the project in terms of (1) time frame, (2) availability of resources (e.g., facilities and ability to schedule, carry out accreditation/reaccreditation site visits, and analyze their results), and (3) management plan.
- Discuss the capability and experience of the applicant organization with similar projects.
- Describe the project management plan, with a time line for tasks and staffing pattern for staff.
- Discuss your organization's capability to obtain and maintain a sufficient number of staff and surveyors to complete the project.
- Provide evidence that your organization's facilities include adequate office space, meeting rooms, and equipment (such as personal computers, automated data processing capability, photocopying equipment, and FAX machines) to accomplish project goals.

Section D: Performance Assessment and Data (15 points)

- Document your ability to collect and report on the required performance measures as specified in Section I-2.1 of this RFA. Describe your plan for data collection, management, analysis and reporting. Specify and justify any additional measures or instruments you plan to use for your grant project.
- Describe how data will be used to manage the project and assure continuous quality improvement.
- Describe your plan for conducting the performance assessment as specified in Section I-2.2 of this RFA and document your ability to conduct the assessment.

NOTE: Although the budget for the proposed project is not a review 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: Literature Citations. This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

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. Be sure to show that no more than 5% of the total grant award will be used for data collection and performance assessment. An illustration of a budget and narrative justification is included in Appendix E of this document.

Section G: Biographical Sketches and Job Descriptions.

- 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 PHS 5161-1 instruction page, available on the SAMHSA Web site.

Section I: 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 I of your application, using the guidelines provided below.

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 eight bullets below. Appendix C of this RFA provides a more detailed discussion of issues applicants should consider in addressing the seven bullets 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 bullets, 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.

- Identify foreseeable risks or adverse effects due to participation in the project and/or in the data collection (performance assessment) activities (including physical, medical, psychological, social, legal, and confidentiality) and provide your procedures for minimizing or protecting participants from these risks. Identify plans to provide guidance and assistance in the event there are adverse effects to participants.

- ❑ Describe the target population and explain why you are including or excluding certain subgroups. Explain how and who will recruit and select participants.
- ❑ State whether participation in the project is voluntary or required. If you plan to provide incentives/compensate participants, specify the type (e.g., money, gifts, coupons), and the value of any such incentives. 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 to be 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. (See Appendix C: Confidentiality and Participant Protection.)
- ❑ Describe data collection procedures, including sources (e.g., participants, school records) and the data collecting setting (e.g., clinic, school). Provide copies of proposed data collection instruments and interview protocols in **Appendix 1** of your application, “Data Collection Instruments/Interview Protocols.” State whether specimens such as urine and/or blood will be obtained and the purpose for collecting the specimens. If applicable, describe how the specimens and process will be monitored to ensure both the safety of participants and the integrity of the specimens.
- ❑ Explain how you will ensure privacy and confidentiality of participants’ records, data collected, interviews, and group discussions. Describe where the data will be stored, safeguards (e.g., locked, coding systems, storing identifiers separate from data), and who will have access to the information.
- ❑ Describe the process for obtaining and documenting consent from adult participants and assent from minors along with consent from their parents or legal guardians. Provide copies of all consent forms in **Appendix 2** of your application, “Sample Consent Forms.” If needed, give English translations.
- ❑ Discuss why the risks are reasonable compared to expected benefits 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 of 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>.

Applicants whose projects must comply with the Human Subjects Regulations must, in addition to the bullets above, 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 clients 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.

2. REVIEW AND SELECTION PROCESS

SAMHSA applications are peer-reviewed according to the evaluation criteria listed above. For those programs where the individual award is over \$100,000, applications also must be reviewed by the appropriate National Advisory Council.

Decisions to fund a grant are based on:

- the strengths and weaknesses of the application as identified by peer reviewers and, when applicable, approved by the Center for Substance Abuse Treatment's National Advisory Council; and
- availability of funds.

VI. ADMINISTRATION INFORMATION

1. AWARD NOTICES

After your application has been reviewed, you will receive a letter from SAMHSA through postal mail that describes the general results of the review, 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 Grant Award, signed by SAMHSA's Grants Management Officer. The Notice of Grant 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; or
 - requirements to address problems identified in review of the application.

- 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. You are encouraged to complete the survey and return it, using the instructions provided on the survey form.

3. REPORTING REQUIREMENTS

In addition to the data reporting requirements listed in Section I-2.1, you must comply with the following reporting requirements:

3.1 Progress and Financial Reports

- Grantees must provide quarterly, annual and final progress reports in electronic and hard copies. The final progress report must summarize information from the annual reports, describe the accomplishments of the project, and describe next steps for implementing plans developed during the grant period.

- Grantees must provide annual and final financial status reports. These reports may be included as separate sections of annual and final progress reports or can be separate documents.

- SAMHSA will provide guidelines and requirements for these reports to grantees at the time of award and at the initial grantee orientation meeting after award. SAMHSA staff will use the information contained in the reports to determine the grantee’s progress toward meeting its goals.

3.2 Government Performance and Results Act (GPRA)

The Government Performance and Results Act (GPRA) mandates accountability and performance-based management by Federal agencies. To meet the GPRA requirements, SAMHSA must collect performance data (i.e., “GPRA data”) from grantees. The performance requirements for SAMHSA’s OTP grant program are described in Section I-2.1 of this document under “Data Collection and Performance Measurement.”

3.3 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:

Alina Walizada
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration

1 Choke Cherry Road
Room 2-1090
Rockville, MD 20857
(240) 276-2755
alina.walizada@samhsa.hhs.gov

For questions on grants management issues contact:

Kathleen Sample
Office of Program Services, Division of Grants Management
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Room 7-1089
Rockville, Maryland 20857
(240) 276-1407
kathleen.sample@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. If you do not adhere to these requirements, your application will be screened out and returned to you without review.

- Use the PHS 5161-1 application form.
- 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 Section IV-6 of this announcement under “Submission of Electronic 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. Failure to adhere to the following guidelines will not, in itself, result in your application being screened out and returned without review. However, 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.

- The 10 application components required for SAMHSA applications should be included and submitted in the following order:
 - § Face Page (Standard Form 424 v2, which is in PHS 5161-1)
 - § Abstract
 - § Table of Contents
 - § Budget Form (Standard Form 424A, which is in PHS 5161-1)
 - § Project Narrative and Supporting Documentation
 - § Appendices
 - § Assurances (Standard Form 424B, which is in PHS 5161-1)
 - § Certifications
 - § Disclosure of Lobbying Activities (Standard Form LLL, which is in PHS 5161-1)
 - § Checklist (a form in PHS 5161-1)

- Applications should comply with the following requirements:
 - § Provisions relating to confidentiality and participant protection specified in Section V-1 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 PHS 5161-1.
- Pages should be typed single-spaced in black ink 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. Appendices 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 Appendices 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-6 of this document. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. 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 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 www.Grants.gov apply site, on the Help page. In addition to the User Guide, you may wish to use the following sources for help:

- By e-mail: support@Grants.gov
- By phone: 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7:00 a.m. to 9:00 p.m. Eastern Time, Monday through Friday, excluding Federal holidays.

If this is the first time you have submitted an application through Grants.gov, you must complete four 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; 3) Credential Provider registration; and 4) Grants.gov registration.

It is strongly recommended that you submit your grant application using Microsoft Office products (e.g., Microsoft Word, Microsoft Excel, etc.). If you do not have access to Microsoft Office 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 **15,450** 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., “Appendices 1-3”, “Appendices 4-5.”

Ensure all pages in your application are numbered consecutively, with the exception of the standard forms in the PHS-5161 application package. **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. You may also submit a back-up paper submission of your application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV-3 of this announcement. The paper submission must be clearly marked: **“Back-up for electronic submission.”** The paper submission must conform with all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

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. **Include the Grants.gov tracking number in the top right corner of the face page (SF 424 v2) for any paper submission. 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.**

The Grants.gov Web site does not accept electronic signatures at this time. Therefore, you must submit a signed paper original of the face page (SF 424 v2), the assurances (SF 424B), and hard copy of any other required documentation that cannot be submitted electronically. **You must include the Grants.gov tracking number for your application on these documents with original signatures, on the top right corner of the face page, and send the documents to the following address. The documents must be received at the following address within 5 business days after your electronic submission.** Delays in receipt of these documents may impact the score your application receives or the ability of your application to be funded.

For United States Postal Service:

Crystal Saunders, Director of Grant Review
Office of Program Services
Substance Abuse and Mental Health Services Administration
Room 3-1044
1 Choke Cherry Road
Rockville, MD **20857**
ATTN: Electronic Applications

For other delivery services, change the zip code to 20850.

If you require a phone number for delivery, you may use (240) 276-1199.

Appendix C – Confidentiality and Participant Protection

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 target population(s) 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 **Appendix 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 **Appendix 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

Applicants may also have to comply with the Protection of Human Subjects Regulations (45 CFR 46), depending on the evaluation and data collection procedures proposed and the population to be served.

Applicants must be aware that even if the Protection of Human Subjects Regulations do not apply to all projects funded, the specific performance assessment design proposed by the applicant may require compliance with these regulations. 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>.

Applicants whose projects must comply with the Protection of Human Subjects Regulations must describe the process for obtaining Institutional Review Board (IRB) approval fully in their applications. While IRB approval is not required at the time of grant award, these applicants will be required, as a condition of award, to provide the documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP) and that IRB approval has been received prior to enrolling any clients in the proposed project.

General information about Protection of Human Subjects Regulations can be obtained on the Web at <http://www.hhs.gov/ohrp>. You may also contact OHRP by e-mail (ohrp@osophs.dhhs.gov) or by phone (240/453-6900). SAMHSA-specific questions related to Protection of Human Subjects Regulations should be directed to the program contact listed in Section VII of this RFA.

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.

- Implement syringe exchange programs, such as the purchase and distribution of syringes and/or needles.
- 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

ILLUSTRATION OF A SAMPLE DETAILED BUDGET AND NARRATIVE JUSTIFICATION TO ACCOMPANY SF 424A: SECTION B FOR 01 BUDGET PERIOD

OBJECT CLASS CATEGORIES

Personnel

Job Title	Name	Annual Salary	Level of Effort	SAMHSA Funded	Non-Federal Sources	TOTAL
Project Director	J. Doe	\$30,000	1.0	\$30,000	\$-0-	
Clinical Director	J. Doe			\$-0-	In-Kind	
Secretary	Unnamed	\$18,000	0.5	\$-0-	\$ 9,000	
Counselor	R. Down	\$25,000	1.0	\$25,000	\$-0-	
SUBTOTAL				\$55,000	\$9,000	
Enter Personnel subtotal on 424A, Section B, 6.a.						\$64,000
<u>Fringe Benefits</u> (24%)				\$15,360	\$-0-	
SUBTOTAL				\$15,360	\$-0-	
Enter Fringe Benefits subtotal on 424A, Section B, 6.b.						\$15,360
<u>Travel</u>						
2 trips for SAMHSA Meetings for 2 Attendees (Airfare @ \$600 x 4 = \$2,400) + (per diem @ \$120 x 4 x 6 days = \$2,880)						
Local Travel (500 miles x .24 per mile)				\$5,280	\$-0-	
				\$-0-	\$120	
[Note: Current Federal Government per diem rates are available at www.gsa.gov .]						
SUBTOTAL				\$5,280	\$120	
Enter Travel subtotal on 424A, Section B, 6.c.						\$ 5,400
<u>Equipment</u> (List Individually)						
"Equipment" means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals the lesser of (a) the capitalization level established by the governmental unit or nongovernmental applicant for financial statement purposes, or (b) \$5000.						
SUBTOTAL				\$-0-	\$-0-	
Enter Equipment subtotal on 424A, Section B, 6.d.						\$-0-

ILLUSTRATION OF DETAILED BUDGET AND NARRATIVE JUSTIFICATION (cont'd.)

Supplies

Office Supplies	\$500	\$-0-
Computer Software – Microsoft Word	\$-0-	500

Enter Supplies subtotal on 424A, Section B, 6.e. \$1,000

CONTRACTUAL COSTS

Evaluation

Job Title	Name	Annual Salary	Level of Effort	SAMHSA Funded	Non-Federal Sources	TOTAL
Evaluator	J. Wilson	\$48,000	.05	\$24,000	\$-0-	
Other Staff		\$18,000	1.0	\$18,000	\$-0-	

Fringe Benefits (25%) \$10,500 \$-0-

Travel

2 trips x 1 Evaluator (\$600 x 2)	\$ 1,200	\$-0-
Per Diem @ \$120 x 6	720	\$-0-
Supplies (General Office)	500	\$-0-

Evaluation Contractual Direct Costs \$54,920 \$-0-
 Evaluation Contractual Indirect Costs (19%) \$10,435 \$-0-

Evaluation Contract Subtotal **\$65,355**

SUBTOTAL \$65,355 \$-0- \$65,355

Training

Job Title	Name	Annual Salary	Level of Effort	SAMHSA Funded	Non-Federal Sources	TOTAL
Coordinator	M. Smith	\$ 12,000	0.5	\$12,000	\$-0-	
Admin. Asst.	N. Jones	9,000	0.5	9,000	\$-0-	

Fringe Benefits (25%) 5,250 \$-0-

Travel

2 Trips for Training		
Airfare @ \$600 x 2	\$1,200	\$-0-
Per Diem \$120 x 2 x 2 days	480	\$-0-
Local (500 miles x .24/mile)	120	\$-0-

Supplies

Office Supplies	\$500	\$-0-
Software (Microsoft Word)	\$500	\$-0-

Training Contractual Direct Costs Subtotal \$40,025 \$-0- **\$40,025**
 Training Contractual Indirect Costs Subtotal \$-0- \$-0- **\$-0-**

ILLUSTRATION OF DETAILED BUDGET AND NARRATIVE JUSTIFICATION (cont'd.)

SUBTOTAL	\$105,380	\$-0-	\$105,380
Enter Contractual subtotal on 424A, Section B, 6.f.			\$105,380
	SAMHSA Funded	Non-Federal Sources	TOTAL
<u>OTHER</u>			
Rent (500 Sq. Ft. x \$9.95)	\$ 4,975	\$-0-	
Telephone	\$ 500	\$-0-	
Maintenance (e.g., van)	\$-0-	\$ 2,500	
Audit	\$-0-	\$ 3,000	
Consultants = Expert @ \$250/day X 6 day (If expert is known, should list by name)	\$ 1,500	\$-0-	
SUBTOTAL	\$6,957	\$5,500	
Enter Other subtotal on 424A, Section B, 6.h.			\$12,475
<u>TOTAL DIRECT CHARGES</u> (sum of 6.a-6.h)			
Enter Total Direct on 424A, Section B, 6.i.			\$192,640
<u>INDIRECT CHARGES</u>			
15% of Salary and Wages (copy of negotiated Indirect Cost Rate Agreement attached) [\$64,000 X 15% = \$9,600]			
Enter Indirect Costs subtotal of 424A, Section B, 6.j.			\$9,600
Enter TOTALS on 424A, Section B, 6.k. (sum of 6i and 6j)			\$202,240

JUSTIFICATION

PERSONNEL - Describe the role and responsibilities of each position.

FRINGE BENEFITS - List all components of the fringe benefit rate.

EQUIPMENT - List equipment and describe the need and the purpose of the equipment in relation to the proposed project.

SUPPLIES - Generally self-explanatory; however, if not, describe need. Include explanation of how the cost has been estimated.

TRAVEL - Explain need for all travel other than that required by SAMHSA.

CONTRACTUAL COSTS - Explain the need for each contractual arrangement and how these components relate to the overall project.

OTHER - Generally self-explanatory. If consultants are included in this category, explain the need and how the consultant's rate has been determined. If rent is requested, provide the name of the owner of the building/facility. If anyone related to the project owns the building which is a less than arms length arrangement, provide cost of ownership/use allowance.

INDIRECT COST RATE - If your organization has no indirect cost rate, please indicate whether your organization plans to: a) waive indirect costs if an award is issued; or b) negotiate and establish an indirect cost rate with DHHS within 90 days of award issuance.

OTHER SOURCES – If other non-Federal sources of funding, including match or cost sharing as a total operating budget is included, provide the name of the source, e.g., in-kind, foundation, program income, Medicaid, State funds, applicant organization, etc., and explain its use.

CALCULATION OF FUTURE BUDGET PERIODS
(based on first 12-month budget period)

Review and verify the accuracy of future year budget estimates. Increases or decreases in the future years must be explained and justified. (NOTE: salary cap of \$186,600 is effective for all FY 2008 awards.)

	First 12-month Period	Second 12-month Period	Third 12-month Period
Personnel			
Project Director	30,000	30,000	30,000
Secretary*	9,000	18,000	18,000
Counselor	25,000	25,000	25,000
TOTAL PERSONNEL	64,000	73,000	73,000

*Increased from 50% to 100% effort in 02 through 03 budget periods.

Fringe Benefits (24%)	15,360	17,520	17,520
Travel	5,400	5,400	5,400
Equipment	-0-	-0-	-0-
Supplies**	1,000	520	520

**Increased amount in 01 year represents costs for software.

Contractual			
Evaluation***	65,355	67,969	70,688
Training	40,025	40,025	40,025

***Increased amounts in 02 and 03 years reflect the increase in client data collection.

Other	1,500	1,500	1,500
Total Direct Costs	192,640	205,934	208,653
Indirect Costs (15% S&W)	9,600	9,600	9,600
TOTAL COSTS	202,240	216,884	219,603

The Federal dollars requested for all object class categories for the first 12-month budget period are entered on Form 424A, Section B, Column (1), lines 6a-6i. The total Federal dollars requested for the second through the fifth 12-month budget periods are entered on Form 424A, Section E, Columns (b) – (e), line 20. The RFA will specify the maximum number of years of support that may be requested.