Cross-Site Evaluation of the Minority Substance Abuse/HIV Prevention Program

OMB Supporting Statement

Part A. Justification

A1. Circumstances Necessitating Data Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting approval from the Office of Management and Budget (OMB) for the revision and reinstatement of data collection activities for the cross-site study of the Minority HIV/AIDS Initiative (MAI), which includes both youth and adult questionnaires. This revision includes the addition of 4 cohorts, changes to the data collection procedures based on intervention duration, and the addition of two questions on binge drinking behavior. The instruments were also modified to include five items for adults and two items for youth on military families and deployment that were recently approved by OMB under the CSAP National Outcomes Measures (NOMs) (OMB # 0930-0230). The current approval for the full cross-site was under OMB No. 0930-0298, which expired on April 30, 2012.

This cross-site study supports two of SAMHSA's eight Strategic Initiatives: Prevention of Substance Abuse and Mental Illness, and Data, Outcomes, and Quality. The participating MAI grantees are community based organizations who serve high risk minority populations with the goal of preventing substance abuse, which is a risk factor for acquiring HIV. They do this by implementing evidence-based prevention interventions which have been proven to be effective and measuring their outcomes. Specifically, the primary objectives of the cross-site study are to:

- Determine the success of the MAI in preventing, delaying, and/or reducing the substance use among the target populations.
- Measure the effectiveness of evidence-based programs and infrastructure development
 activities such as: outreach and training, mobilization of key stakeholders, substance abuse and
 HIV/AIDS counseling and education, referrals to appropriate medical treatment and/or other
 intervention strategies (i.e., cultural enrichment activities, providing educational and vocational
 resources, and computer-based curricula).
- Assess the process of adopting and implementing the Strategic Prevention Framework (SPF) with the target populations.

This program is authorized by Section 516 of the Public Health Service Act, as amended, and subject to the availability of funds. It was supported by the Congressional Black Caucus through its Conference Report on H.R. 4328, Making Omnibus Consolidated and Emergency Supplemental Appropriations Act, for FY 1998 (House of Representatives, October 19, 1998), to address prevention and treatment needs

of minority communities that are disproportionately affected by HIV/AIDS. It builds on previously authorized programs addressing these issues (discussed below).

Although several Federal agencies have mandates to fund projects targeting minority and minority reentry populations who are at risk for substance use and HIV/AIDS, very little is known about the efficacy of such programs once they become widely disseminated. Prior efforts to evaluate Federal substance use prevention initiatives targeting at-risk populations have focused on highly specific program models and strictly defined target populations or have been hampered by lack of valid instrumentation and poor study design. Although models have been disseminated to community-based agencies (that typically implement these programs under less rigorous and controlled parameters), measures and efforts to assess outcomes were inadequate and/or not sufficiently designed to determine the true impact of these interventions. In addition, the link between substance abuse and HIV/AIDS outcomes has not been evaluated for these programs or in local community settings.

Literature searches within SAMHSA's three centers and with five other Federal agencies were conducted to identify studies with similar goals and expected outcomes. These searches have indicated that no similar study has been conducted which examines prevention initiatives regarding substance abuse (SA) in relation to HIV/AIDS. Even though the present cross-site study is unique from others that have been conducted in the field, information generated from these literature searches has sharpened the present cross-site study design and enhanced the likely utility of the results.

The cross-site study is scientifically appropriate, employs measures to safeguard the privacy and security of participants' responses, and supports the program and study needs of multiple Federal agencies. Sample size, respondent burden, and intrusiveness have been minimized to be consistent with cross-site study objectives. To minimize and control respondent burden and to ensure the user-relevance of questions, every effort has been made to coordinate cross-site data collection with local data collection efforts, including pilot testing.

The cross-site study results will have significant implications for the substance abuse and HIV/AIDS prevention field, the allocation of grant funds, and other evaluation activities conducted by multiple Federal, State, and local government agencies. The results will be used to develop Federal policy in support of CSAP program initiatives, inform the public of lessons learned and findings, improve existing programs, and promote replication and dissemination of effective prevention strategies.

Background

Epidemiological studies on the dynamics of substance abuse and HIV/AIDS demonstrate a continued need to reach out to communities of color, particularly to those reporting high rates of HIV/AIDS and other sexually transmitted diseases (STDs). The Centers for Disease Control and Prevention (CDC) reported that although African Americans are only 13% of the U.S. population, they accounted for 52% of all HIV/AIDS cases diagnosed in 2008 and that Hispanics accounted for 19 percent of AIDS cases in 2008, despite making up only 15 percent of the U.S. population.

Of particular concern to communities of color is the return of ex-offenders, otherwise known as the reentry population. Despite the efforts of correctional facilities to prevent sexual risk-taking behavior and substance abuse among incarcerated persons, a significant number engage in high-risk activities (such as IDU, tattooing, and coerced sexual activity), placing others at risk for HIV transmission. Each year,

many of these persons, unaware of their HIV status, return to their communities and re-engage in substance abuse and other high-risk behaviors, putting others at an even greater risk for HIV/AIDS transmission.

Regardless of the mode of HIV transmission HIV/AIDS is an infectious disease that has drastic long-term medical, economic, and social consequences on minority populations. Meeting the challenges posed by HIV/AIDS requires close coordination with existing local, State, and territorial substance abuse and HIV/AIDS prevention programs. SAMHSA is working to improve access to quality services by increasing outreach and service capacity to at risk populations of color. Grantees are asked to use of the Strategic Prevention Framework as a method to prevent and reduce both substance abuse and the transmission of HIV/AIDS that will lay the necessary foundation for effective and sustainable prevention service delivery in the context of substance abuse and HIV/AIDS.

In FY 2009, the MAI Cohort 7 Program funded 55 five-year grants and in FY 2010 the MAI Cohort 8 Program funded 5 five-year grants to community-based organizations. These programs combined planning and services funding and required all grantees to participate in this cross-site study. They are expected to provide leadership and coordination on the planning and implementation of the SPF that targets minority populations and the minority re-entry population in communities of color with a high prevalence of substance abuse and HIV/AIDS. The primary objectives of the cross-site study are to:

- Assess the process of adopting and implementing the SPF with the target population,
- Measure the effectiveness of specified intervention strategies such as cultural enrichment, educational and evaluation activities, vocational resources, and/or computer-based curricula, and
- Determine the success of the MAI in delaying, preventing, and/or reducing the use of alcohol, tobacco, and other drugs among the target population.

The MAI Cohort 9 (35 five-year grants) and 10 (27 five-year grants) programs build on previous SAMHSA/CSAP HIV/AIDS grant programs that provided substance abuse and HIV/AIDS planning and prevention services for minority populations.

The goal for Cohort 1 grants was to provide services. Goals for Cohorts 2-10 grants were to add, increase, or enhance integrated substance abuse and HIV prevention services by providing supportive services and by strengthening linkages among service providers for at-risk minority populations. HIV Cohorts 1-3 fell under SAMHSA/CSAP's umbrella OMB Clearance Document 0930—0208. Since neither the HIV Cohort 4 nor the Cohort 5 Programs were cross-site studies, they did not require OMB clearance.

These past programs have enabled CSAP to make great progress in providing innovative, community-based drug prevention, planning, and intervention services to minority populations at risk for substance abuse and HIV/AIDS. HIV 6 grantees successfully improved on a number of key outcomes. See tables below.

Table 1. Risk of Harm From Substance Use

Percentage of HIV Cohort 6 Program Participants Ages 12 or Older Reporting Moderate or Great Risk of Harm From Having Five or More Drinks of Alcohol Once or Twice a Week and From Smoking Marijuana Once or Twice a Week at Baseline and Exit

| | | Ages 12 to 17 | | | | Ages 18 | or Older | | |
|-----------|----------|----------------------------------|------|------|---------|---------------|----------|--------|-----|
| | | Valid N Baseline % Exit % Change | | | Valid N | Baseline % | Exit % | Change | |
| Alcohol | Cohort 6 | 1,792 | 75.9 | 82.2 | 6.2 | 10,111 | 83.9 | 87.7 | 3.8 |
| Marijuana | Cohort 6 | 1,796 | 65.8 | 73.4 | 7.6 | 9,428 | 68.2 | 76.0 | 7.8 |

Source: HIV Cohort 6 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

Table 2. Disapproval of Peer Substance Use

Percentage of HIV Cohort 6 Program Participants Ages 12 to 17 Who Somewhat or Strongly Disapprove of Their Peers Using Alcohol Nearly Every Day, Trying Marijuana and Using Marijuana Regularly at Baseline and Exit

| | | Ages 12 to 17 | | | |
|-----------------------|----------|---------------|------------|--------|--------|
| | | Valid N | Baseline % | Exit % | Change |
| Alcohol | Cohort 6 | 1,570 | 66.4 | 67.4 | 1.0 |
| Trying Marijuana | Cohort 6 | 1,542 | 58.4 | 60.8 | 2.4 |
| Regular Marijuana Use | Cohort 6 | 1,523 | 56.6 | 58.2 | 1.6 |

Source: HIV Cohort 6 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

Table 3. Changes in Past 30-Day Substance Use

Average Days of Substance Use During the Past 30-Days by HIV Cohort 6 and 7 Program Participants Ages 12 or Older at Baseline and Exit

| | | Youth | | | Adult | | | | |
|-------------------------------------|----------|---------|------------|--------|--------|---------|---------------|--------|--------|
| | | Valid N | Baseline % | Exit % | Change | Valid N | Baseline % | Exit % | Change |
| Alcohol | Cohort 6 | 3,151 | 1.3 | 1.0 | -0.2 | 9,406 | 2.8 | 2.3 | -0.5 |
| Marijuana | Cohort 6 | 2,064 | 2.1 | 1.6 | -0.5 | 10,942 | 2.3 | 1.7 | -0.6 |
| Illicit Drugs (Excluding Marijuana) | Cohort 6 | 2,115 | 0.8 | 0.6 | -0.2 | 11,056 | 2.1 | 1.5 | -0.6 |
| Prescription Drugs | Cohort 6 | N/A | | N/A | | 10,860 | 0.5 | 0.4 | -0.1 |

Source: HIV Cohort 6 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

Note 3: The "Youth" category includes respondents ages 12 to 17 with the exception of alcohol use; for this measure, the category is comprised of participants ages 12 to 20. The "Adult" category includes respondents ages 18 or older with the exception of alcohol use; for this measure, the category is defined as ages 21 or older.

Table 4. Risk of Harm From Unprotected Sex

Percentage of HIV Cohort 6 Program Participants Ages 18 or Older Reporting Moderate or Great Risk of Harm From Unprotected Sex at Baseline and Exit

| | | | Ages 18 | or Older | |
|---|-------|---------|------------|----------|--------|
| | | Valid N | Baseline % | Exit % | Change |
| Perception of Risk of Unprotected Anal Sex | ort 6 | 10,976 | 90.8 | 93.7 | 2.9 |
| Perception of Risk of Unprotected Oral Sex | ort 6 | 10,986 | 79.7 | 83.6 | 3.9 |
| Perception of Risk of Unprotected Vaginal Sex | ort 6 | 10,979 | 87.9 | 91.2 | 3.4 |

Source: HIV Cohort 6 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

Table 5. Participants Reporting Protected Sex

Percentage of HIV Cohort 6 Program Participants Ages 18 or Older Reporting That Their Last Sexual Encounter Was Protected at Baseline and Exit

| | | Ages 18 or Older | | | |
|-----------------------|----------|------------------|------------|--------|--------|
| | | Valid N | Baseline % | Exit % | Change |
| Protected Anal Sex | Cohort 6 | 3,015 | 39.2 | 43.2 | 4.0 |
| Protected Oral Sex | Cohort 6 | 8,360 | 24.7 | 29.0 | 4.4 |
| Protected Vaginal Sex | Cohort 6 | 9,228 | 38.0 | 42.8 | 4.7 |

Source: HIV Cohort 6 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

Table 6. Sexual Self Efficacy, HIV Knowledge and Hepatitis Knowledge

Average Sexual Self Efficacy, Hepatitis Knowledge and HIV Knowledge Scale Scores at Baseline and Exit for HIV Cohort 6 and 7 Participants Ages 12 or Older

| | | | Ages 12 to 17 | | | | Ages 18 o | r Older | |
|----------------------|----------|---------|---------------|--------|--------|---------|---------------|---------|--------|
| | | Valid N | Baseline % | Exit % | Change | Valid N | Baseline % | Exit % | Change |
| Sexual Self-Efficacy | Cohort 6 | 1,983 | 13.8 | 14.1 | 0.3 | 10,724 | 11.3 | 12.1 | 0.8 |
| Hepatitis Knowledge | Cohort 6 | 2,088 | 30.5 | 60.2 | 29.7 | 11,075 | 47.0 | 65.8 | 18.8 |
| HIV Knowledge | Cohort 6 | 2,116 | 58.0 | 75.5 | 17.5 | 11,082 | 75.9 | 83.1 | 7.2 |

Source: HIV Cohort 6 and 7 participant-level data, matched cases only through FY 2010

Note 1: Valid N refers to the total number of valid responses to the survey item.

Note 2: Figures within the "Change" column are calculated as the difference between exit and baseline. Minor discrepancies are due to rounding.

The Cohort 6, 7, 8, 9 and 10 MAI Programs differ substantially from the earlier programs in that they target very different populations and call for the use of the SPF and evidence-based programs. While these grantees have substantial flexibility in choosing evidence-based programs, they are all required to base their projects on the five steps of SAMHSA's SPF to build service capacity specific to substance abuse and HIV/AIDS prevention services.

A2. Purpose and Use of Information

The Minority HIV/AIDS Initiative (MAI) cross-site study will involve not only collecting information on the planning and delivery of the evidence based programs, but also assessing their effectiveness. Grantees will be conducting ongoing monitoring and analysis of their projects to assess program effectiveness, including Federal reporting of the GPRA, SAMHSA/CSAP NOMs, as well as HIV Counseling and Testing. The specific purpose of this study, as well as the planned use of findings from this evaluation, is described in this section.

CSAP has a well-established history of incorporating evaluation findings and conclusions into the policy process, and the results of this study will be used similarly. It is designed to provide more specific information on the effectiveness of diversely funded programs in preventing and/or reducing substance use and related problems, CSAP will use the evaluation results to influence public policy studies, and programming as they relate to the provision of youth and adult services. More specifically, the research will support the following uses by CSAP:

- Findings will be used in required NOMs and GPRA performance reporting, and will be presented in annual reports to Congress.
- Findings regarding SPF implementation will be used to assess prevention, delay or reduce substance use, influence positive sexual behaviors, change substance use attitudes, and reduce associated problem sexual and substance use behaviors, as well as to assess the effectiveness of currently funded prevention programs. Furthermore, the common utilization of substance use outcome measures (from CSAP, GPRA, and NOMs) will allow CSAP to compare initiatives (including the previous HIV/AIDS programs) as to their success in achieving their goals. Such extensive cross-initiative information will be used to set broad prevention policy priorities.
- Findings concerning the substance use and sexual behavior risk factors as both program
 outcomes and mediating factors will be used to refine policy and shape future program
 funding announcements. In addition, the findings may be used to provide
 recommendations to States regarding selection of evidence-based programs, since a
 portion of Block Grant monies given to the States must be spent on SA prevention.
 Additional monies have been awarded to some States through the Strategic Prevention
 Framework State Incentive Grants (SPF-SIG).
- Findings concerning program inputs (intervention strategies, frequency, and length) will be used to provide program guidelines (e.g., through RFA's) and to plan appropriate technical assistance services for programs/States.

 Findings will support CSAP publications and materials on prevention practices that are an important resource for public and private organizations involved in the design and implementation of prevention programming for youth and adults.

In sum, the findings from the study will be a crucial resource for CSAP in setting prevention policy priorities, measuring performance, and designing and promoting optimally effective prevention program initiatives. Although the cross-site study is designed primarily to address CSAP program requirements, the study results will be useful to other Federal, State, and community agencies involved in efforts to prevent or reduce substance use among youth and adults. While some of these agencies are specifically interested in providing preventive health services, others have a more general interest in approaches or strategies that have been proven effective.

CSAP has and plans to continue using the data collected under this initiative to improve program performance, meet statutory/regulatory requirements, and enhance the current knowledge base on prevention programs for minority populations at risk for substance use and HIV/AIDS and increase public awareness about factors associated with substance use and HIV risk behaviors among minority populations. In order to improve program performance, CSAP shares the most recent program performance data and related outcomes to grantees, stakeholders, and other Federal officials at annual MAI grantee meetings. These findings are then used to inform program direction and identify and address weaknesses. For example, the most recent performance data indicated a need to improve non-user stability rates for alcohol and decrease illicit drug use rates. As a result, the two most recent MAI cohorts, namely the Ready to Respond Initiative and the Capacity Building Initiative, are specifically focused on increasing HIV prevention interventions with high-risk populations as well as the capacity to implement integrated, evidence-based substance abuse interventions. This change in focus will ultimately increase program performance in these areas.

CSAP also plans to continue using the data collected under this initiative to meet statutory/regulatory requirements. Specifically, SAMHSA must collect these data to meet its federal requirements specified in the ADAMHA Reorganization Act of 1992 (PL 102-321), as well as the GPRA Modernization Act of 2010 (PL 111-352). According to the ADAMHA Reorganization Act of 1992 (Section 516) "the Director of the Prevention Center, shall: (a) provide assistance to communities to develop comprehensive long-term strategies for the prevention of substance abuse; and (b) evaluate the success of different community approaches toward the prevention of such abuse." These requirements specify that SAMHSA must evaluate this program, identify strengths and weakness, and assist the Director in making decisions necessary to strengthen the program and comply with this federal statute. In addition, data collected through the MAI help SAMHSA comply with federal reporting requirements related to appropriations (i.e. GPRA). Currently, SAMHSA uses data collected through the MAI to report on 14 performance measures.

Through this initiative, CSAP has and plans to continue to enhance the current knowledge base on the effectiveness of prevention programs for minority populations at risk for SA and

HIV/AIDS as well as increase public awareness about factors associated with substance use and HIV risk behaviors among minority populations. Information collected under this initiative will be used by CSAP and other Federal agencies in their efforts to assess specific intervention services in the prevention or reduction of substance use and HIV/AIDS among minority community and re-entry populations. CSAP plans to provide evidence and conclusions for disseminating optimally effective prevention policy and programs. Information will also be useful to policymakers, who need to learn how to extend their reach into and among these populations.

The MAI program findings on substance use and HIV risk behaviors have and continue to be widely disseminated through presentations and publications to increase public awareness. For the past four years, CSAP has presented findings obtained from data collected through the MAI at the annual National Prevention Network Research Conference (NPNRC). The NPNRC is attended by leading researchers in the field of prevention, as well as representatives from every Single State Authority. Last year, CSAP presented findings on the Cohort 6 re-entry population at the annual American Public Health Association Meeting. Lastly, using data from Cohort 3, CSAP and contract staff jointly published two peer-reviewed articles, one in the Journal of Alcohol & Drug Education on a latent structure analysis of substance use and HIV risk behaviors among high-risk minority adults, and the other in the Journal of the National Medical Association on a structural model analysis of HIV risk behaviors among sexually active minority adolescents. These articles exemplify CSAP's continued contributions to the prevention field and to increased public awareness of factors associated with substance use and HIV risk behaviors among specific minority populations, through the use of data collected by HIV grantees. In the next several months, the MAI program will be able to provide information on what are the most effective substance abuse and HIV prevention interventions for specific target populations and under what conditions

CSAP will also share the outcome information and lessons learned with other Federal DHHS agencies, including but not limited to SAMHSA's Center for Substance Abuse Treatment (CSAT), the National Institute on Drug Abuse (NIDA), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF), which administers several drug-related programs targeted at hard-to-reach and at-risk populations.

Beyond Federal DHHS agencies, CSAP plans to share outcomes and lessons learned with other Federal agencies that provide services to high-risk youth:

- The Department of Justice (DOJ) and their Office of Juvenile Justice and Delinquency Prevention (OJJDP), which funds projects that target high-risk youth and often involve SA prevention interventions.
- The Department of Housing and Urban Development (HUD), which supports two major initiatives (the National Youth Sports Program and the Public Housing Drug Elimination Program) that target youth at risk of substance use and provide positive alternative activities for at-risk youth in a drug-free environment.

- The Department of Education (DOE), which funds the Safe Schools/Healthy Students effort (focused on violence and substance abuse prevention) under the Drug Free Schools and Communities Act.
- State and local program planners and the public through publications and a public-use data set.

State and local agencies also have significant responsibilities for design and implementation of prevention programs for youth and adults. The results of the MAI cross-site findings may be useful in a variety of ways to State and local agencies, including:

- Policymakers in State and local governments will have evidence of the impact of various evidence-based programs and infrastructure development models on preventing or reducing use and HIV/AIDS among minority and re-entry youth and adults residing in communities of color. The evidence will be useful in setting prevention policy priorities.
- Program planners in State and local governments and in community-based organizations will have comparative evidence on the effectiveness of different models for the provision of youth and adult services. This information will be useful in developing funding guidelines and direct service programs.
- National, not-for-profit, nonprofit, voluntary, and professional organizations will have an accurate portrayal of the program inputs that are required to establish successful programs targeting minority and re-entry youth and adults residing in communities of color. This information will promote optimally effective prevention program design.

Implementing evidence-based programs in minority community settings presents challenges (i.e., maintaining rigor in design and instrumentation, as well as maintaining the ability to measure impact), given the need for local adaptations for specific target populations. Using the lessons learned from the previous programs, the current focus is on enhancing the effectiveness of specific interventions for reducing risk factors and/or enhancing the factors that protect against substance use and HIV/AIDS among the minority youth and adult population as well as the minority youth and adult re-entry population.

Changes from previous OMB submission

Data will be collected from approximately 35,433 respondents served by the 122 grantees at three time points (baseline or program entry, program exit, and three to six months post-exit) for interventions lasting 30 days or longer, two time points (baseline and exit) for interventions lasting between 2 and 29 days and one time point (exit only) for single session (one day) interventions. The CSAP National Outcomes Measures (NOMs) Adult and Youth questionnaires, which have been approved by OMB (OMB # 0930-0230) for use in all CSAP evaluation studies, will be used to measure substance use and risk factors associated with substance use among program participants. These NOMs data are used to report on Government Performance and Results Act (GPRA) and findings across CSAP programs.

For this program, these cross-site instruments are augmented with additional scales to measure other important risk and protective factors uniquely associated with HIV/AIDS among minority populations and minority re-entry populations in communities of color. The youth (covering ages 12-17) questionnaire contains 125 questions, of which 28 relate to HIV/AIDS and the adult questionnaire contains 118 items, of which 47 relate to HIV/AIDS. Two new questions have been added to both the youth and adult questionnaires to address SAMHSA's need to collect information on binge drinking behavior, not covered under any prior OMB package. According to National Institutes on Alcohol Abuse and Alcoholism, binge drinking is defined as a pattern of drinking that brings a person's blood alcohol concentration (BAC) to 0.08 percent or above. This typically happens when a man consumes 5 or more drinks and a woman consumes 4 or more drinks in about 2 hours.

These questions are:

During the past 30 days, on how many days did you have 4 or more drinks on the same occasion? [By 'occasion,' we mean at the same time or within a couple of hours of each other]

and

During the past 30 days, on how many days did you have 5 or more drinks on the same occasion? [By 'occasion,' we mean at the same time or within a couple of hours of each other].

Grantees will report these data online through the CSAP Prevention Management Reporting and Training System (PMRTS). Participants in interventions lasting 30 days or longer will be required to complete the entire questionnaire (three sections). Participants in interventions lasting between 2 and 29 days will complete sections one and two of the questionnaire and participants in single-session interventions will complete section one and 3-5 questions from section two. Participants are free to refuse to respond to the entire survey or to particular items in the survey. See breakdown below:

| INTERVENTION DURATION | LENGTH | DEFINITION | SECTIONS OF SURVEY TO BE ADMINISTERED |
|---|-------------------------|--|---|
| Single Session Intervention | 1 day or less | A direct service intervention that lasts one day or less. Participants may receive multiple services during the session, but do not continue in a CSAP HIV grant funded activity for more than one day. | Section One: Facts about You 3 to 5 questions from Section Two: Attitudes & Knowledge |
| Multiple Session Brief Intervention | Less than 30 days | The participant should receive at least two HIV Grant funded sessions or service encounters. The period of time between the first session or encounter and the last session or encounter should be two to 29 days . | Section One: Facts about YouSection Two: Attitudes & Knowledge |
| Multiple Session Long Intervention | 30 days or more | The participant should receive at least two HIV Grant funded sessions or service encounters. The period of time between the first session/encounter and the last session/encounter should be 30 days or more. | Section One: Facts about You Section Two: Attitudes & Knowledge Section Three: Behavior & Relationships |

A3. Use of Information Technology

It is anticipated that technical infrastructure and data management skills will vary across grantee sites. To maximize data accuracy and reliability, online data entry tools will be designed for the instruments being submitted for clearance. These tools will be made available to grantees through CSAPS's Prevention Management Reporting and Training System (PMRTS).

The PMRTS requires only a web browser and access to the Internet. Users are able to access the system 24 hours a day, 7 days weeks, aside from scheduled maintenance windows through the use of an encrypted username and password. Upon logging into a system-assigned account, grantees can: enter anonymized survey data (e.g., no names or social security numbers are entered into the system); perform a bulk file upload of their survey data; and run reports to export their survey data in CSV format. The system also allows CSAP Project Officers to run reports about overall responses, and Coverage Reports that provide information about which grantees have submitted data into the PMRTS.

The tools in the PMRTS have been designed to reflect the structure of the instruments, and to allow the entry of data from completed survey forms directly into the system through the use of radio buttons corresponding to response options. The system will automatically quantify the selected response options and store the numeric codes in a SQL server for subsequent extraction, cleaning, and analysis.

The PMRTS is maintained by CSAP's Data Collection, Analyses, and Reporting Contract (DCAR). The data entered online by grantees are periodically extracted) for cleaning, record linkage, and analysis. Grantees have two options for accessing the data they entered online. In the first option, grantees can download the raw data they have entered online (as soon as it is submitted) in spreadsheet form. They can also access their data from the cleaned analysis files posted on PMRTS under password protection. In the second option, grantees can upload complete data files to the PMRTS. For this option, grantees are required to use a standard codebook while preparing the data, thus ensuring that uploaded data files have the same numeric coding and variable naming conventions as the data entered using the online tools.

These online data entry tools reduce the grantees' burden by facilitating the data entry process and minimizing coding and variable naming errors. They also allow grantees without access to data management/analysis software to accurately quantify the information in completed survey forms. The DCAR will then conduct cross-site analyses to determine outcomes for the program as a whole.

The electronic multi-site data collection process will increase the efficiency and practical utility of the assessment of these programs. The CSAP multi-site questionnaires have been developed and used by grantees in previous HIV cohort programs and have been demonstrated to work efficiently and effectively. Based on the feedback of the HIV pilot, the questionnaires and procedures for electronic transmission of data files have been improved to increase efficiency and minimize burden on both training participants and grantee staff. Additionally, all MAI grantee's proposals were reviewed for assurances of participant protections by an independent peer review committee, and any identified issues about inadequacies were resolved prior to funding

A4. Efforts to Identify Duplication

CSAP conducted an extensive literature search, consulted with staff in Federal agencies and organizations that work with substance use and HIV/AIDS prevention programs, and discussed the proposed program with substance abuse prevention experts. Specifically, CSAP:

- Conducted a comprehensive literature search of completed and ongoing studies of substance use and HIV/AIDS prevention programs targeting youth and adults and found insignificant duplication with this cross-site study. All studies were examined closely to take advantage of applicable methods and to identify any methodological problems that might detract from the validity, generalizability, or application of results.
- Consulted with staff in CSAT, CDC, NIAID, NIDA, ACF, OJJDP, HUD, DOE and DOJ. None of
 these Federal organizations has conducted a cross-site outcome evaluation of
 prevention and early intervention programs targeting minority youth and minority reentry youth residing in communities of color that is similar to the one being proposed
 for this study.

• Staff attended national meetings at which completed, ongoing, or contemplated evaluations were discussed and found insignificant duplication with the proposed study.

In summary, CSAP did not identify any redundancy in that there were no precedents for a cross-site study of projects similar to the one being proposed. Others suffered severe methodological problems such as low sample sizes, lack of dosage monitoring, and/or lack of published/reliable/valid measures and scales that make it unlikely that current information will be published or released among the scientific community or in respected journals, government publications, etc. Thus, it is clear that the data to be collected will be unique to the CSAP MAI programs, collected only for the CSAP programs, and not available elsewhere. The data collected through the multi-site effort will be non-duplicative, minimize burden on respondents, and be of use to both CSAP and the communities of color.

A5. Involvement of Small Entities

This data collection will have no significant impact on small entities.

A6. Consequences If Information Collected Less Frequently

The data will be collected from participants in interventions lasting 30 days or longer at three points in time: baseline (program entry), program exit and three to six months post-exit, two time points (baseline and exit) for interventions lasting between 2 and 29 days and one time point (exit only) for single session (one day) interventions. Failure to collect the information from all participants at all three points in time will result in missed opportunities and lessons learned on how to provide a quality improvement mechanism for CSAP to continually monitor and refine its prevention programs to ensure they meet the needs of minority populations and minority re entry populations at risk for SA/HIV/AIDS residing in communities of color. Data collected at all three points in time is essential for 30-day or longer interventions, as it will also demonstrate whether sustainable results can be achieved over time after the program has ended, and if so, for which types of interventions and populations. Since this information is all based on self-reporting, response accuracy will be assessed by employing internal consistency and validity checks embedded in the questionnaires. Likewise, SAMSHA recognizes that response rates will decline overtime when data are collected over an extended period of time.

Without this information:

- CSAP will not be able to determine the extent to which it can prevent, reduce, and/or delay substance abuse and, in turn, reduce other risky behaviors that can lead to HIV/AIDS infection among minority populations and minority re-entry populations residing in communities of color.
- CSAP will not be able to monitor the quality of its prevention programs and determine how they can be improved to ensure continued success at meeting the needs of minority populations at risk for HIV/AIDS.

- CSAP will not be able to describe fully the range of prevention services used and the efficacy of evidence-based programs.
- CSAP will not be able to ascertain if participants are more knowledgeable about HIV/AIDS and how they relate to SA as a result of program participation.
- CSAP will not be able to identify those prevention services that are most effective and identify the potentially unique needs of minority populations residing in the community and minority re-entry populations.
- CSAP will not be able to meet its Federal reporting requirements to DHHS, OMB, and Congress.

Several measures are in place to ensure that grantees do not falsify responses or selectively choose respondents. As part of its grant application process SAMHSA/CSAP requires grantees to describe the methods by which data will be collected, how data collection forms will be administered and by whom. These proposals are reviewed and any identified issues about inadequacies are resolved prior to funding. After funding, grantees must submit their data using CSAP's Prevention Management Reporting and Training System (PMRTS). The PMRTS conducts internal consistency and validity checks on the data entered into the system to ensure the accuracy of the data submitted, and CSAP project officers (PO's) monitor the data submitted by grantees periodically to check for accuracy. Additionally, all MAI grantees are required to collect and report data from all intervention participants, a census is required not a sample of participants. Thus, grantees cannot selectively choose respondents; they must gather data from all respondents.

Additionally, to determine if there is a non-response bias, data from respondents will be compared with available data on non-respondents. In addition, a two-step analysis strategy will be used to control for attrition bias. First, baseline characteristics of all participants will be compared with baseline characteristics of participants who completed the programs. These two sets of data records will be compared with respect to baseline values of demographic characteristics, incarceration/reentry status, levels of risk and protection, and levels of substance use. Second, baseline factors found to differ significantly between the two sets of records will be included in all of the models and only model estimates net of these factors will be reported in the final evaluation results. This approach minimizes selectivity biases due to program attrition in reported program effects.

A7. Consistency With Guidelines in 5 CFR 1320.5(d) (2)

This information collection fully complies with 5 CFR 1320.5(d) (2).

A8. Consultation Outside the Agency

A8a. Federal Registry Announcement

The notice required in 5 CFR 1320.8(d) was published in the Federal Register on May 17, 2012 (Vol. 77, p. 29355). No comments were received.

A8b. Consultations Outside the Agency

The multi-site study and questionnaire design were based on initial consultation with SAMHSA experts from CMHS and CSAT, and on pilot testing with the previous HIV Cohorts. Other SAMHSA HIV program experts, such as Jenifer Fiedelholtz of OPPB and David R Robertson of CSAT (among others), were consulted on the following issues:

- Draft study design plan and privacy/data security procedures; plan for coordinating and collecting data; measures to be used to assess outcomes; and mediating factors
- Suitability of proposed assessment instruments
- Materials and nuances of prevention programs that may be relevant to finalizing the methods to be used in conducting the cross-site study and reporting study findings
- Means of minimizing the burden on project staff and program participants
- Identification of efforts to ensure user relevance of results.

CSAP consulted with other experts on SA and HIV/AIDS, as well as other Federal agencies with related programs or mandates, including NIDA, ACF, CDC, DOJ, OJJDP, HUD, and the DOE. Consultations resulted in the refinement of measures and the coordination of Federal data needs.

A9. Payment to Respondents

To maximize response rates MAI grantees will offer non-monetary incentives valued at \$10 to all respondents. These incentives are specific to their target population and may include: T-shirts, food coupons, movie tickets or other types of merchandise that do not exceed \$10 in value. No monetary incentives are provided to respondents.

The use of incentives has proven necessary and effective in recruiting respondents to participate in this type of research, and incentives are effective in increasing response rates for data collection activities (Castiglioni, Pforr, and Krieger, 2008; Goldenberg, McGrath, and Tan, 2009; Laurie and Lynn, 2009; McGonagle, Schoeni, Couper, and Mushtag, 2011; Rogers, 2011). Additionally, incentives are used routinely by SAMHSA and by other Federal agencies. For example, the Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS (TCE-HIV) Multisite Evaluation offers participants gift cards valued at \$10-\$20 (OMB # 0930-0317, expires 11/30/13) and the Cross-Site Evaluation of the Garrett Lee Smith Memorial

Suicide Prevention and Early Intervention Program offers participants incentives valued at \$10-\$20 (OMB # 0930-0286, expires 8/31/13).

A10. Assurance of Confidentiality

SAMHSA has statutory authority to collect data under the Government Performance and Results Act (Public Law 1103(a), Title 31) and is subject to the Privacy Act for the protection of this data. As part of its grant application process, SAMHSA/CSAP requires grantees to describe the procedures they will use to ensure the privacy and protection of participant data. These include by whom and the methods by which data will be collected; how data collection forms will be administered; where data will be stored; who will/will not have access to information; and how the identity of participants will be safeguarded. Consent forms will include language about privacy and that the data collection is voluntary and will not affect participation in direct service programs. Data are collected through self report

The information from grantees and all other potential respondents will be kept private through all points in the data collection and reporting process. All data will be closely safeguarded, and no institutional or individual identifiers will be used in reports. Only aggregated data will be reported. SAMHSA and its contractors will not receive identifiable client records. Provider-level information will be aggregated to, at the least, the level of the grant/cooperative agreement-funding announcement.

A11. Questions of a Sensitive Nature

SAMHSA's mission is to improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for substance abuse and mental illnesses, including co-occurring disorders, in order to improve health and reduce illness, death, disability, and cost to society. In carrying out this mission it is necessary for service providers to collect sensitive items such as use of alcohol or other drugs. The data that will be submitted by each grantee will be based in large part on data that most programs are already routinely collecting. This primarily includes data on client demographics, substance abuse history, services received, and outcomes in order to understand the needs of participants and to measure the impact of services. Grantees are required to have adequate consent procedures in place, and these procedures include obtaining and documenting active parental/guardian consent when necessary. SAMHSA review committees will not approve nor will SAMHSA fund a site without adequate provisions for meeting Federal policies regarding consent. Review committees consider the following participant protection (PP) criteria:

- 1. Protect participants from potential risks,
- 2. Fair selection of participants,
- 3. Absence of coercion,
- 4. Data collection,
- 5. Privacy and confidentiality, and

6. Adequate consent procedures.

Applications are coded: no PP concerns or comments; PP comments or PP concerns. Before an application can be funded, the applicant must address in writing any PP comments or concerns raised to the CSAP's participant protection officer's satisfaction. Until this is done, they are barred from funding especially if the application is coded with "concerns". The CSAP participant protection officer reviews their response to issues raised by the peer review committee. If they respond to the protection officer's satisfaction, the bar on funding is lifted.

SAMHSA follows procedures similar to those used by CDC and DoEd regarding parental consent for youth: adherence to state and local regulations.

A12. Estimates of Annualized Hour Burden

Tables 7a and 7b show the estimated annualized burden for data collection. The evaluation data will be collected through questionnaires administered to youth and adult program participants. Youth and Adults in interventions lasting 30 days or longer will complete questionnaires three times, taking an average of 50 minutes for baseline, exit, and follow-up questionnaires. Participants in interventions lasting 2-29 days will complete questionnaires two times taking an average of 30 minutes to complete. Single-session intervention participants will complete one questionnaire at exit taking approximately 15 minutes to complete. Approximately 11,811 adults and youth are expected to respond annually across all 3 intervention types. Based on HIV Cohort 6 results, the expected response rates at exit are 62% and 37% at the three to six month follow-up in interventions lasting 30 days or longer. The total burden for this three year clearance request is 45,147 hours and the average annualized burden is 15,049 hours, as noted in the following table.

Table 7a. Estimates of Annualized Hour Burden by Intervention Length

| Intervention Length | Number of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Hour Burden | Hourly Wage Cost | Total Hour Cost | |
|------------------------|-----------------------------|--------------------------------|--------------------|--------------------------|-------------------------|------------------------|-----------------------|--|
| 30- Days or Mo | re Intervention | | | | | | | |
| Base line | 7,937 | 1 | 7,937 | 0.84 | 6,667 | \$16.57 | \$110,474 | |
| Exit | 4,887 | 1 | 4,887 | 0.84 | 4,105 | \$16.57 | \$68,021 | |
| Follow-up | 2,942 | 1 | 2,942 | 0.84 | 2,471 | \$16.57 | \$40,949 | |
| Subtotal | 7,937 | | 15,766 | | 13,243 | | \$219,444 | |
| 2 to 29 Day Inte | ervention | | | | | | | |
| Base line | 1,416 | 1 | 1,416 | 0.51 | 722 | \$16.57 | \$11,966 | |
| Exit | 872 | 1 | 872 | 0.51 | 445 | \$16.57 | \$7,369 | |
| Subtotal | 1,416 | | 2,288 | | 1,167 | | \$19,335 | |
| Single Day Inte | Single Day Intervention | | | | | | | |
| Exit | 2,458 | 1 | 2,458 | 0.26 | 639 | \$16.57 | \$10,590 | |
| Annualized Total | 11,811 | | 20,512 | | 15,049 | | \$249,369 | |

Note 1: Due to rounding, totals and subtotals may appear to be different than the sum of its components by a one point range.

Note 2: The total hour cost is based on the estimated number of adults that will take the survey and does not include cost for youth participants.

Table 7b. Estimates of Annualized Hour Burden by Survey Type

| | Number of | Total | Total Hour | Hourly | Total Hour |
|---------------------------|-------------|-----------|------------|-----------|------------|
| Questionnaire | Respondents | Responses | Burden | Wage Cost | Cost |
| Annualized | 9,685 | 16,820 | 12,340 | \$16.57 | \$204,476 |
| Total Adult | 7,003 | 10,620 | 12,340 | \$10.57 | \$204,470 |
| Annualized Total Youth | 2,126 | 3,692 | 2,709 | N/A | N/A |
| Annualized Total | 11,811 | 20,512 | 15,049 | | \$204,476 |

The burden estimate presented in Tables 7a and 7b is based on Cohort 6 findings. The approximate distribution of adults and youth in Cohort 6 is 82% adults and 18% youth. There will be no direct cost to youth or adults for participating in the study.).

The estimates for hourly wage of respondents is based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2010 National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/current/oes nat.htm

A13. Estimates of Annualized Cost Burden to Respondents

There will be no capital, start up, or operation and maintenance costs incurred by the adults and youth participating in this study. The PMRTS online data collection tool will be available at no cost to grantees.

A14. Estimates of Annualized Cost to the Government

The total contract award for the DCAR will cover all aspects of the study design, planning, data collection, and analysis, with the annualized cost of \$500,000. These costs cover the following activities: assistance to study sites in cooperation with the national evaluation; cleaning and processing of outcome data from study sites; data analysis and reporting; and development of public use data and documentation.

It is anticipated that the Government Project Officers who oversee the projects will expend time in assisting the DCAR and grantees in appropriately responding to the measures. The GPO overseeing the HIV Cross-site will expend a portion of time overseeing the analysis of the HIV Cross-site data, as well as updating the data collection procedures for new cohorts. Data analysis activities include processing the data received from the various programs, as well as conducting statistical analysis. These costs are broken out in the table below. Annual hours are based on a 40-hour work week for 48 weeks per year. It is estimated that 8 CSAP Project

Officers will be involved for approximately 2 percent of their time at an average annual salary of \$110,000. The annualized total cost to the government will be \$523,040.

Table 8. Estimated Annualized Cost to the Government

| Position | Percent FTE | Annual Hours | Rate | Total Annual Cost |
|--------------------------------------|----------------|-----------------|------|-------------------------|
| DCAR Cross-site | NA | NA | NA | \$500,000 |
| HIV Cross-site GPO | 10% | 192 | \$40 | \$7,680 |
| HIV GPOs (Based on Estimated 8 GPOs) | 2.50% | 384 | \$40 | \$15,360 |
| Total | | | | \$523,040 |

A15. Changes in Burden

This is a reinstatement of a previously approved data collection. Currently there are 0 burden hours in the OMB inventory. Previously, there were 16,770 hours in the OMB inventory. CSAP is requesting 15,049 burden hours to continue this cross-site study. The decrease of 1,721 hours is due to an adjustment. The original estimate was based on all participants being enrolled in 30-day or longer interventions. The adjustment also accounts for interventions lasting less than 30 days.

A16. Time Schedule, Analysis and Publication Plans

Analysis Plans

The defining characteristic of this cross-site study is the sharing of a common protocol, a common set of performance measures, common outcome objectives, and common evaluation questions by all participating grantees. This study differs from more traditional multi-site clinical trials because each individual grantee will select Evidence Based Interventions (EBI) and Diffusion of Effective Behavioral Interventions (DEBI) that are adapted to the needs of the particular target population, setting, and organizational characteristics. This multi-site evaluation does not test a single intervention that has different settings, rather it is testing a category of interventions that have similar outcome objectives but that use different approaches to accomplish those objectives.

Analysis of a multiple-site data set requires a complex set of interrelated tasks. Planning for these tasks must be flexible, and must allow adjustments as the opportunities and challenges presented by the empirical realities of the data set are discovered. While multi-site studies provide strong opportunities for knowledge generation (because of the ability to contrast intervention and implementation variation in a single study), they also present significant evaluation challenges. This study recognizes those challenges and anticipates solutions as they

will apply to the 122 participating grantees. All SAMHSA grantees are required to collect and report certain data so that the Agency can meet its obligations under the Government Performance and Results Modernization Act of 2010 (GPRA).

In SAMHSA programs, which are often client level/participant interventions that are dramatically different from one group to another may have insufficient population receiving a specific intervention to justify a sample. Populations from each group may not be similar and would not be appropriate to infer general findings about the successes or failures of a program because of the uniqueness of each group. Within populations, sample sizes may be too small to properly sample, leading to large sample variance and errors in findings about the programs. In these cases, where programs differ from group to group, it is important to gather data sufficient to draw statistically accurate conclusions about how the programs are performing and about what characteristics of the program may matter to the success of the program.

In addition to the GPRA, data collected by grantees will be used to demonstrate how SAMHSA's grant programs are reducing disparities in access, service use, and outcomes nationwide. To accomplish this, SAMHSA expects grantees to utilize their data to (1) identifying subpopulations (i.e., racial, ethnic, sexual/gender minority groups) vulnerable to health disparities and (2) implement strategies to decrease the differences in **access, service use**, and **outcomes** among those subpopulations. There will be subpopulations where sample size is too small to properly sample and where a census would be necessary obtain relevant and reliable outcome data.

Statistical Procedure Determination. As a multi-site design, the CSAP initiative collects information at two levels of observation: 1) across individuals, and 2) within individuals at three points in time for individuals in interventions lasting 30 days or longer and two points in time for individuals in interventions lasting between 2 and 29 days. The units of observation also have a hierarchical relation. Individual level units (youth and adults) are nested within program sites and points in time are nested within individuals.

The proposed analysis includes several distinct steps:

- First, pooled analyses of outcomes will be conducted to assess the (controlled) presence
 of significant factors in growth curve trends for youth and adults participating in
 prevention interventions.
- Second, the heterogeneity of outcomes across sites will be assessed to determine if
 outcomes for substance use or important protective factors significantly differ across
 sites. If there are significant differences, hypotheses will be developed to explain those
 differences and conduct multivariate analyses on: a) clusters of sites that share
 characteristics hypothesized to be contributors to effectiveness, and/or b) individual
 sites that exhibit combinations of principles and practices hypothesized as contributors
 to effectiveness.
- Additional analyses will test the sensitivity of effectiveness models to differences in participant characteristics.

Statistical Test Determinations. Both the structural equation model (SEM) approach to estimating the trajectory parameters and the hierarchical linear model (HLM) approach that can consider time to be nested within an individual will be the key analytic methods conducted for this multi-site evaluation (MSE) (Bollen, 1989; Chou, Bender, & Pentz, 1998). This hierarchical data set presents flexible analysis opportunities as well as some analytic challenges. As the primary statistical tool, the plan is to apply multi-level regression [e.g., SEM and HLM] models. This technique allows for the identification of individual effects, controls for co-variates (e.g., propensity scores to control for non-equivalence across intervention groups), and tests for interaction effects with the different types of interventions and youth or adult characteristics that may mediate the impact of the intervention. HLM also provides excellent capacity for analyzing longitudinal, repeated measures designs (Willett, Singer, and Martin, 1998), can accommodate missing data at individual data points, and allow adjustments for different individual intervals between follow-up data points. Tests for attrition bias and selective attrition are conducted at each follow-up point.

A two-step analysis strategy will be used to control for attrition bias. First, baseline characteristics of all participants will be compared with baseline characteristics of participants who completed the programs. These two sets of data records will be compared with respect to baseline values of demographic characteristics, incarceration/reentry status, levels of risk and protection, and levels of substance use. Second, baseline factors found to differ significantly between the two sets of records will be included in all of the models and only model estimates net of these factors will be reported in the final evaluation results. This approach minimizes selectivity biases due to program attrition in reported program effects.

The MSE dataset will provide the flexibility to conduct analyses that provide useful evidence concerning the general effectiveness of prevention in reducing risk factors and promoting (developing) protective factors that could potentially affect SA or HIV/AIDS risk or transmission. The dataset will also be able to assess the variation in this effectiveness between interventions among the project sites, and offer potential explanations of that variation (e.g., amount of contact, type of intervention approach).

Given that target populations and community contexts vary by grant site, the multi-site dataset will contain data from a wide range of program participants in terms of their demographic, socioeconomic, and cultural characteristics. All multivariate models will include all of the factors that account for the differences among groups. Those factors that are found to have a significant effect on outcomes will be identified and interaction terms will be constructed to represent differences in program effects due to recruitment strategy. This analytic strategy will allow the evaluation study to take into consideration the mediating effects of a broad range of factors on program outcomes. The inclusion of these demographic, socioeconomic, and cultural control variables and interaction terms in the models will also ensure that final results are not biased toward the outcomes of groups with relatively large numbers of data records.

Many of the grantees are targeting African American and Hispanic/Latino populations and populations who have just been released (re-entry) from the criminal justice system. Youth

between the ages of 12 and 17 and adults aged 18 and over are included in the cross-site study design. Varieties of methods are being used to recruit participants. Most sites report that participants will be identified from SA treatment programs, referrals from collaborations with criminal justice systems and other involved agencies, and/or through site-specific geographical areas that were identified through the SPF Step 1 needs assessment conducted during the first year of the grant. This needs assessment will identify key risk factors, including risk for substance use, HIV/AIDS transmission, and economic disadvantage. Step 2 will assess capacity to provide services. For Steps 3 and 4 (planning and implementation), grantees are allowed to select and adopt a variety of evidence-based prevention intervention approaches to fit the needs of their program participants/clients.

A multi-level analysis approach [e.g., SEM and HLM] will be used to investigate the effects of program characteristics on participant outcomes. Characteristics hypothesized to have a bearing on program effects, such as choice of prevention strategy and type of grantee organization, will be included in the dataset together with participant-level baseline, exit, and followup survey data. Nesting participant-level data within program-level data in this fashion will allow the construction of multi-level causal models that simultaneously test for the effects of participant and program characteristics on program outcomes and to identify significant interactions between these two levels.

Assessment of Exit-Only Data from Single-Session Interventions. The single-session data collection protocol requires administration of the questionnaire only at exit. Outcome analysis of these data will compare the exit responses of each participant with a norm constructed using the baseline responses to the item provided by a comparable group of participants from the same site who were in longer interventions (and hence, took both the baseline and exit surveys).

Publication Plans

The MAI cross-site study results will be made available to the public through publications and conference presentations. The following journals carry articles on SA prevention and HIV/AIDS and are expected to serve as potential vehicles for distribution of study results: Journal of Substance Abuse Treatment, International Journal of Addictions, Journal of Community Psychology, Journal of Adolescent Research, Journal of Adolescent Health, Preventive Medicine, Evaluation Review, Policy Studies Review, and the American Journal of Public Health. Study results could also be published in other journals that focus on HIV/AIDS. These include The Journal of the American Sexually Transmitted Disease Association, Health Education and Behavior, AIDS: Official Journal of the International AIDS Association, AIDS Education and Prevention, The Journal of Sex Research, AIDS Care, Psychological and Socio-Medical Aspects of AIDS/HIV, and Current Opinion in HIV and AIDS. Study results also are targeted for publication in journals focusing on infectious diseases. These include, among others, The Journal of the American Microbiological Association and Journal of Infectious Diseases.

The study results will be distributed through presentations at annual conferences of national and international public health organizations, such as the Society for Prevention Research, the American Public Health Association, the National Association of Alcohol and Drug Abuse Counselors, The National Prevention Network, the American Evaluation Association, and HIV/AIDS national meetings as well as regional and State SA prevention and treatment associations. HIV/AIDS meetings could include, among others, CDC Annual Conferences on AIDS and Conferences of the International AIDS Society. Results could also be presented at meetings focusing on infectious diseases such as annual meetings of the American Society of Microbiology.

Documents will also be prepared and published on behalf of the government (CSAP) through the Government Printing Office (GPO) for Federal agency and public use. Findings will also be available via OMB's Website: www.expectmore.gov, as well as in annual reports to Congress and the performance detail sections of annual SAMHSA budgets as they become publicly available.

Timeline

The MAI is a five-year grant program (see Table 4). Years I and 2 are devoted to Steps 1, 2 and 3 of the SPF, namely conducting the needs assessment, capacity building, and planning, respectively. Years 3, 4, and 5 are devoted to Steps 4 and 5, implementation and evaluation, respectively.

Table 9. Project Timeline

| Activity | Cohorts 7 | Cohort 8 | Cohort 9 | Cohort 10 |
|--------------------|-----------|----------|----------|-----------|
| Needs | FY 2009 | FY 2010 | FY 2011 | FY 2011 |
| Assessment, | | | | |
| Capacity Building, | | | | |
| Planning | | | | |
| OMB Clearance | FY 2012 | FY 2012 | FY 2012 | FY 2012 |
| Obtained, | | | | |
| Implementation | | | | |
| Implementation | FY 2010 | FY 2011 | FY 2011 | FY 2012 |
| Analysis and | FY 2011 | FY 2012 | FY 2012 | FY 2013 |
| Reporting | | | | |

A17. Display of Expiration Date

The expiration date will be displayed.

A18. Exceptions to Certification Statement

No exceptions are required.

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