SUPPORTING STATEMENT FOR
SCREENING, BRIEF INTERVENTION, REFERRAL AND TREATMENT (SBIRT)
CROSS-SITE EVALUATION

A. JUSTIFICATION

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment (CSAT) is requesting approval from the Office of Management and Budget (OMB) for the data collection activities for the Cross-Site Evaluation of the "Screening, Brief Intervention, Referral and Treatment (SBIRT)" program. These activities are the administration of baseline and follow-up surveys of patients receiving SBIRT services and a survey of practitioners in health care providers who are delivering SBIRT services.

The SBIRT program is authorized under Section 509 of the Public Health Service Act, as amended. (See Attachment 1.) The program also addresses Healthy People 2010, Volume II (Part B: Focus Area 26--Substance Abuse). For demand reduction, the 2005 National Drug Control Strategy (NDCS) emphasizes: (1) preventing initiation of illegal drug use; (2) getting treatment resources where they are needed; and (3) attacking the economic basis of the drug trade (ONDCP, 2005). SBIRT's focus on early intervention and treatment continues to be a vital component of the NDCS demand reduction initiatives.

Federal programs, including those operated by SAMHSA/CSAT, have tended to emphasize either universal prevention strategies aimed at those who have never initiated use (Mrazek and Haggerty, 1994) or specialist treatment for those who are dependent (Gerstein and Harwood, 1990). Little attention has been paid to the large group of individuals who use drugs but are not, or not yet, dependent and who could successfully reduce drug use through "early intervention". (Klitzner et al., 1992; Fleming, 2002). There is an emerging body of research and clinical experience that supports use of the SBIRT approach as providing effective early intervention for persons at risk for, or diagnosed with, a Substance Use Disorder (Substance Abuse or Dependence) (e.g., Barry, 1999; Babor and Higgins-Biddle, 2000; Bernstein et. al, 1997; Zweben and Fleming, 1999; Broskowski and Smith, 2001; Heather, 2001; Dennis, et al., 2002; Babor, 2002; Blow, 1998; Fleming 2002; Breslin, et al., 2002; Degutis, 2003; Fleming, 2003; Babor, 2004).

The specialist treatment system is often not appropriate for persons at risk for a Substance Use Disorder, nor can that system alone address the needs of all those persons diagnosed with either a Substance Abuse or a Substance Dependence Disorder. Consequently, new program efforts are needed to provide funding to introduce or expand screening and brief intervention and brief treatment for persons at risk for, or diagnosed with, a Substance Use Disorder (Substance Abuse or Dependence). These new program efforts have been initiated in general medical and other community settings (e.g., community health centers, nursing homes, schools and student assistance programs, occupational health clinics, hospitals, emergency departments).

Screening for substance use and misuse among patients in primary care settings offers many potential benefits. It provides an opportunity to educate patients about low-risk consumption levels and the risks of excessive use (DHHS, 1997). Information about the amount and frequency of alcohol or drug consumption may also inform the diagnosis of the patient's presenting condition, and it may alert clinicians to the need to advise patients regarding adverse effects of medication use and other aspects of their treatment. Screening also offers the opportunity for practitioners to take preventive measures proven to be effective in reducing alcohol-/drug-related risks.

Recognizing that treatment needs could be better met through a comprehensive approach to identifying and treating substance use problems across a continuum of severity, SAMHSA's CSAT established the Screening, Brief Intervention, Referral and Treatment (SBIRT) program. CSAT's SBIRT program is a relatively new cooperative agreement grant program designed to help States, Territories, and Tribes expand the continuum of care available for substance misuse and use disorders. The program includes screening, brief intervention (BI), referrals, and brief treatment (BT) for persons at risk for dependence on alcohol or drugs. This evaluation will conduct an assessment on the impact of SBIRT in six States and one Tribal Organization.

The SBIRT program represents a major advance in the basic philosophy of addressing substance use issues and the role of the treatment system. Like other practices developed in tightly controlled research settings, it is important to understand how SBIRT will work best in various settings and under somewhat different approaches. It is also important to examine which models of SBIRT offer the greatest potential to improve the U.S. service system.

Currently, SAMHSA monitors the performance of these SBIRT programs using data collected through the Government Performance and Results Act (GPRA) (OMB No. 0930-0208). Although GPRA data are sufficient for program monitoring, they are not sufficient for establishing best practices of competing programs. The patient and practitioner surveys will produce the key outcome data necessary for a complete evaluation sufficient to establish best practices.

The SBIRT cross-site evaluation of a multiprotocol, multipopulation effort will generate empirically-based knowledge about a variety of interventions and how they function within a variety of populations and contexts, thus broadening SAMHSA's initiatives. The results of clinical trials reported in the literature demonstrate the effectiveness of SBIRT on substance use outcomes in different service delivery settings and with different types of staff (Fleming et al., 1999; Ballesteros et al., 2004; Moyer et al., 2002; D'Onofrio and Degutis, 2002; Saitz et al., 2003). However, that research does not necessarily translate into practice in a full-scale implementation, and those results may not be reproduced outside of small, controlled populations using well-defined components. The literature itself suggests that implementation of SBIRT components and the integration of these components with primary health care and the specialized treatment system faces many challenges (Modesto-Lowe and Boornazian, 2000; Roche and Freeman, 2004; Arndt et al., 2002; Church and Babor, 1995). By linking this evidence base in the literature to the models actually being implemented by the seven sites, the cross-site evaluation will be able to compare program outcomes with the results in the literature and thereby gauge the success and impact of the broader implementation of SBIRT.

2. Purpose and Use of Information

The cross-site evaluation of SBIRT is supported by two interrelated evaluation efforts: a process evaluation and an impact or outcome evaluation. The process evaluation serves the critical role of establishing the overall evaluation's context and consequently aids in the interpretation of findings of the outcome evaluation. The process evaluation also describes the content of grantees' interventions and their theoretical basis. It will analyze the congruence of the individual SBIRT models being implemented to their evidence base in the literature and the fidelity of each grantee's actual implementation to the models they are proposing to implement. The outcome evaluation provides information on what impact the SBIRT interventions had on the grantees, health care providers, and patients involved. The outcome evaluation also provides evidence on how specific provider and programmatic characteristics relate to SBIRT's impact on patient outcomes.

The conclusions of the outcome evaluation are supported by the process evaluation, which provides a theoretical foundation on which the results can be based. In particular, the process evaluation will determine the extent to which evidence-based SBIRT practices are being implemented and thus provide a context and a benchmark for interpreting the results of the outcome analysis. Monitoring and measuring outcomes of fully implemented SBIRT models and showing that they are within ranges for outcomes found in the clinical trials will be a keystone of evidence of the successful implementation and impact of SBIRT. Together, the process and outcome analyses will produce a collage of evidence for how well the evidence-based clinical practices of SBIRT are able to be implemented in a variety of settings and populations.

The complete evaluation will thus allow CSAT to determine the extent to which the SBIRT program has met its objectives of implementing a comprehensive system of identification and care for individuals at all points along the substance use continuum. The evaluation represents the most comprehensive assessment of SBIRT ever undertaken and will provide evidence on the costs, impact, feasibility, and long-run sustainability of SBIRT when implemented on a systems-wide scale. The evaluation will provide CSAT with detailed evidence on which models of SBIRT have the greatest impact for various populations, which components within those models require modification when applied to a new population, and how well the evidence-based models translate into practice.

The cross-site evaluation will specifically help SAMHSA achieve the goals of its Capacity Performance Goals and Matrix Priorities. See Attachment 2. The SBIRT program is designed to help SAMHSA meet the following cross-cutting principles:

- Science to services/evidence-based practices
- Increasing the number of individuals receiving treatment
- Improving the outcomes of those treated

The results of this data collection effort will provide SAMHSA with substantive, technical, and administrative support to transfer science to services concerning public and private sector substance abuse programs. Data collected via both surveys will enable the SBIRT program to increase its effectiveness in meeting the needs of their clients with substance use disorders.

Additionally, the patient survey will provide baseline and follow-up data to inform future policy concerning the development and implementation of SBIRT within a nonsubstance abuse treatment setting.

Outcome data reflect the Agency's desire for consistency in data collected within the Agency. SAMHSA is implementing specific performance domains called the National Outcome Measures (NOMS) to assess the accountability and performance of its discretionary and formula grant programs. These domains represent SAMHSA's focus on the factors that contribute to the success of substance abuse treatment. The SBIRT Cross-site Evaluation will address the following performance domains:

- Abstinence from Drug / Alcohol Use
- Employment / Education
- Crime and Criminal Justice
- Family and Living Conditions
- Access / Capacity
- Retention
- Perception of Care
- Cost Effectiveness
- Use of Evidence-Based Practices

In addition, the Program Assessment Rating Tool (PART) is intended to draw on available program performance and evaluation information to form conclusions about program benefits and recommend adjustment that may improve results. A General Accounting Office report entitled "Program Evaluation – OMB's PART Review Increased Agencies' Attention to Improving Evidence of Program Results", October 2005, recommended that OMB encourage agencies to discuss and implement evaluation plans with OMB and congressional stakeholders.

The patient and practitioner surveys will provide the data necessary to conduct a complete outcome evaluation. The following paragraphs present a description of the surveys.

Patient Surveys: (See Attachments 3 and 4.) While the baseline and follow-up patient surveys will ask similar questions to those recorded in the GPRA data, they will also include additional measures necessary for evaluating the full spectrum of patient outcomes and the moderators and mediators of those outcomes. The patient surveys will collect outcomes more relevant to lower-risk patients than does GPRA, which focuses on a treatment population. As part of the effort to obtain a complete set of outcomes, the patient surveys will include questions representing the domains of the National Outcome Measures (NOMS).

The targeted universe for the SBIRT evaluation patient surveys are patients presenting for health care treatment in each participating grantee, with some exclusions that vary by grantee. Eligibility for the receipt of SBIRT services is limited to patients aged 18 to 64 who are not mentally or physically incapacitated and who are not currently in the custody of law enforcement officers. The patient-level surveys will be administered to a sample of patients at each grantee. All of those receiving the initial survey will be selected for a 6-month follow-up interview. Data collection at the follow-up point is necessary to measure the short- and longer-term outcomes of

the SBIRT programs implemented by the grantees, one of the primary objectives of the SBIRT initiative.

The patient surveys contain questions from the following four surveys and sets of measures:

- National Outcome Measures (NOMs)
- National Survey on Drug Use and Health (NSDUH)
- National Longitudinal Survey of Youth, 1979 (NLSY-79)
- National Vietnam Veterans Longitudinal Study (NVVLS)

In addition, three scales are included in the patient surveys. The Stanford Presenteeism Scale (SPS) (Koopman et al., 2002) measures the productivity of employees, which is often related to substance abuse. The Patient Health Questionnaire (PHQ-8) (Spitzer et al., 1999) is included to gauge depression. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (WHO, 2002) is the measure being used for alcohol and substance abuse.

Practitioner Survey: (See Attachment 5.) All practitioners (e.g., physicians, health educators) in health care providers that deliver SBIRT services at the selected units are eligible to be surveyed. These include health educators, chemical dependency counselors, physicians, nursing staff, and other staff involved in the delivery of SBIRT services. Demographics and educational background characteristics will be collected along with a randomly generated site identification number. The practitioner survey includes sets of questions that attempt to gauge barriers to implementation encountered by the practitioners and training received by the practitioners. The analysis will be based primarily on descriptive statistics on service delivery unit type and practitioner characteristics and attitudes.

3. Use of Information Technology

The baseline patient survey and the practitioner survey will be administered on-site using a computer-assisted personal interview (CAPI). These surveys will be programmed onto Tablet PCs, which are lightweight enough for the survey staff to hold for long periods of time. Patients receiving the initial survey will be selected for a follow-up interview via computer-assisted telephone interviewing (CATI). These computer-assisted methods reduce respondent burden, ensure high-quality data collection, and reduce interviewer errors.

The SBIRT patient surveys will be designed to lead the respondent/interviewer through the interview by means of a set of logically linked screens displayed on the Tablet PCs. Each screen will contain one question. The program will implement logic or fill-ins (based on the values of previous responses) to personalize or tailor the wording of questions and response lists. Wording will also be tailored based on different terminology required for each grantee. This is particularly important for the practitioner survey, which will be addressing different types of staff depending on the SBIRT model being implemented in each grantee.

The program will also specify skip patterns that alter question sequence based on a respondent's answers. To the extent possible, program key question-by-question specifications will be coded as on-screen instructions. In addition to these standard processes, the instrument will be

developed with extensive checks on value ranges and on cross-item consistency. These programming strategies will be used for the patient and practitioner surveys and during the CATI follow-up. Patients who are unable to be contacted by phone at follow-up will be interviewed in person exactly as they were at baseline, using CAPI via Tablet PCs.

3. Effort to Identify Duplication

The SAMHSA SBIRT Cross-Site Evaluation Team conducted an extensive literature review to confirm that the data collected through these sites would not be duplicative of any ongoing national or state-level data collection efforts. Data collected in this evaluation will be unique because of the scale and breadth of the initiative's implementation: nationwide, across a spectrum of provider settings, and across a broad cross-section of populations.

Certain elements of the data collected by grantees on patients receiving SBIRT services as required by the GPRA will be duplicative of elements collected in the patient surveys by the cross-site evaluation. Attempting to link the two data sets (GPRA data and baseline survey data) in order to not duplicate questions, such as demographics, may increase the probability of compromising data security as well as jeopardizing the integrity of the final data because of the possibility of case mismatches, hand-keyed data errors, etc.

In addition, the GPRA data are insufficient for producing a complete evaluation. While the patient surveys will ask similar questions to those recorded in the GPRA data, they will also include additional measures necessary for evaluating the full spectrum of patient outcomes and the moderators and mediators of those outcomes. As part of the effort to obtain a complete set of outcomes, the patient surveys will include questions representing the domains of the National Outcome Measures (NOMS).

5. Involvement of Small Entities

Participation of patients in the SBIRT cross-site evaluation will not be a significant burden on small businesses or small entities or on their workforces.

6. Consequences If Information Collected Less Frequently

Patient Survey: A patient-level survey will be administered to a sample of patients at each grantee. All of those receiving the initial survey will be selected for a 6-month follow-up interview primarily via CATI and via CAPI if necessary. Data collection at these follow-up points is necessary to measure the short- and longer-term outcomes of the SBIRT program.

Following up at 6 months is optimal for producing useful outcome data. Waiting until 6 months after the initial receipt of services allows enough time for any effects of SBIRT to develop, including changes in substance use behavior or secondary outcomes, such as driving under the influence, arrests, and other health care utilization. Alternatively, waiting more than 6 months jeopardizes the validity of the data collected. As time passes, self-reported data become less accurate. Moreover, follow-up response rates, especially among much of the population to which SBIRT is being delivered, decrease over time. Attrition is often systematically correlated with

patient characteristics, which may bias the measurement of changes in outcomes and preclude the generalization of those outcomes to a broader population.

Practitioner Survey: The practitioner survey will be administered to each respondent one time. Because the objective of the practitioner survey is not to monitor trends in variables over time or before and after an intervention, obtaining the data more frequently would be an unnecessary burden. Less frequent data collection would not achieve the SBIRT Cross-Site Evaluation initiative's primary objectives.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

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

8. Consultation Outside the Agency

The notice required by 5 CFR1320.8(d) was published in the *Federal Register* on January 12, 2006 (71 FR 2058-2059). (See Attachment 6 for a copy of the Federal Register notice.) No comments were received in response to this notice.

SAMHSA has made extensive use of experts in the area of substance abuse research to provide guidance on the design and analysis of the cross-site evaluation. An expert panel meeting was held in October 2005 to review the various aspects of the cross-site evaluation, including the evaluation plan, data collection procedures, economic analysis methods, and literature review. The list of experts is provided in Exhibit 1.

Exhibit 1: Expert Panel Members

Expert	Affiliation	Contact Information
Thomas F. Babor, MPH, PhD	Professor University of Connecticut School of Medicine Department of Community Medicine 263 Farmington Avenue Farmington, CT 06030-6325	Phone: 860-679-5459 Fax: 860-679-5451 E-mail: babor@nso.uchc.edu
Janette Baird, PhD	Project Coordinator Rhode Island Hospital Injury Prevention Center Physician's Office Building Suite 334 110 Lockwood Street Providence, Rhode Island 02874	Phone: 401-444-2976 Fax: 401-444-2249 E-mail: jbaird@lifespan.org
Antonio Gual, MD, PhD	University of Barcelona, Spain Alcohol Unit, Neurosciences Institute, Clinic Hospital Villarroel 170 Barcelona, Spain 08021	Phone: 34 932019856 E-mail: tgual@clinic.ub.es
Daniel W. Hungerford, DrPH	Epidemiologist CDC/NCIPC/DIDOP 4770 Buford Highway NE, Mailstop F-41 Atlanta, GA 30033	Phone: 770-488-4142 Fax: 770-488-4338 E-mail: DHungerford@cdc.gov

Expert	Affiliation	Contact Information
Maristela Monteiro, MD, PhD	Regional Advisor on Alcohol and Substance Abuse Pan American Health Organization 525 23rd Street NW Washington, DC 20037	Phone: 202-974-3108 Fax: 202-974-3640 Email: monteirm@paho.org
Margaret M. Murray, MSW	Chief, Health Sciences Education Branch National Institute on Alcohol Abuse and Alcoholism National Institutes of Health 6000 Executive Boulevard Suite 302 Rockville, MD 20854	Phone: 301-443-2594 Email: pmurray@mail.nih.gov
Richard E. Sherman, PhD	SBIRT Project Process Evaluator Illinois Dept. of Human Services, Division of Alcoholism and Substance Abuse 100 West Randolph Street Suite 5-600 Chicago, IL 60618	Phone: 312-814-2290 Fax: 312-814-2419 E-mail: dhsas61@dhs.state.il.us
Robert S. Stephens, PhD	Associate Professor Virginia Tech Department of Psychology 0436 Blacksburg, VA 24060	Phone: 540-231-6304 Fax: 540-231-3652 E-mail: stephens@vt.edu
Gary Zarkin, PhD	Division Vice President RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-5858 Fax: 919-485-5555 E-mail: gaz@rti.org

The experts provided feedback on all aspects of the evaluation, including the patient and practitioner surveys, and their comments were incorporated into later drafts of the surveys. Likewise, grantees were permitted to comment on the surveys throughout the period following the expert panel meeting.

9. Payment to Respondents

Patient Survey: Cash incentives will be used for all baseline interviews ($5) regardless of completing the survey. Patient will be mailed $25 upon completing the follow-up survey. Survey research literature suggests that monetary incentives have a strong positive effect on response rates and no known adverse effect on reliability. Substance abuse research has shown improved response rates when remuneration is offered to respondents. Individuals with substance use issues are typically a harder-to-reach population, and the cash payment at baseline and the potential payment at follow-up should lead to a higher follow-up success rate. Results from the 2001 National Household Survey on Drug Abuse (NHSDA) incentive experiment were reported by Wright et al. (2002); key conclusions from their analyses are summarized below:

The $20 and $40 incentive payments each produced about a 10-point gain in overall response rates when compared with the $0 control group. The overall response rate was significantly higher for $40 than the $20 incentive within many of the subgroups addressed in the analysis. Both incentive payment groups more than paid for themselves due to decreased costs of follow-up and more productive screening resulting from the improved response rates. Incentives

motivate (or obligate) respondents to admit to substance use that they might not have admitted without the incentive.

Practitioner Survey: No cash incentives or gifts will be given to respondents to the practitioner survey.

10. Assurance of Confidentiality

Concern for confidentiality and protection of respondents' rights will play a central part in the implementation of all study components. Research Triangle Institute (RTI) is implementing the cross-site surveys and collecting and analyzing the data and has extensive experience protecting and maintaining the confidentiality of respondent data.

Patient Survey: The process of administering the baseline patient survey is designed to protect confidentiality, reduce patient discomfort and burden, and ensure the collection of quality data. After completing their own data collection and service delivery activities, provider staff who deliver SBIRT services will briefly explain the reason for an additional survey, describe the survey length and process, inform patients of the cash incentive, and obtain verbal permission to perform a "warm handoff" to the RTI survey staff. During the handoff, the SBIRT staff will introduce the patient to the RTI staff and help answer any concerns or questions the patient may have. They will be in a private location to ensure confidentiality.

The actual handoff process will be tailored to each grantee's clinical patient flow to reduce patient and staff burden and ensure confidentiality. Part of the handoff will include the presentation of a one-page handout that the patient will keep that describes the SBIRT evaluation and survey objectives. (See Attachment 7.) This handout will include the OMB approval expiration dates, the statement of survey burden, and the statement that the study is federally sponsored. On this handout, the SBIRT service provider will use a color coding scheme to inform the RTI staff of the patient's SBIRT risk category as determined by the screener score. After the SBIRT staff leave, the RTI staff will invoke a new patient survey record on the Tablet PC, entering the risk category of the new patient. A randomly generated identification number will be assigned to the patient to link the baseline data with the follow-up data. The next screen will be the informed consent form, in Attachment 8, which the patient will read and electronically sign if the patient understands and agrees with its contents. The informed consent form informs the patient that the survey is voluntary and that he or she may drop out at any point.

All patient data will be entered into the Tablet PC, which will be encrypted and password protected. Each day, the RTI staff will upload the data over a secure network connection directly to a server at RTI headquarters where they will also be encrypted and password protected. Details on RTI's network security procedures and the Tablet PC/data transmission security protocols are presented in Attachment 9. Using protected electronic data is the most secure form of data management because it eliminates the possibility of paper documents being lost by the survey staff or of data being lost in transit or delivered to an incorrect location. Additionally, no further data entry will be necessary, which not only eliminates errors in transmission but also removes one more potential breach of confidentiality because no data entry staff is needed.

To conduct follow-up interviews with patients, it will be necessary to collect detailed contact information during the baseline survey. These contact data will include a patient's full name, current and anticipated addresses, primary and alternate phone numbers, and similar contact information for a friend or relative who would know the patient's contact information should the patient's stated information become outdated through a move or other event. No medical record numbers and Social Security Numbers will be collected, and none of the information will be used to link the patient to any other database.

All contact information will be stored separately from the patients' responses to protect the confidentiality of their responses to sensitive questions. The identification number assigned to each patient will be stored with the contact information. At follow-up, after the patient has been properly identified, the RTI staff administering the survey will then create a new observation that contains only the identification number. By this number, the baseline data for each patient will be linked to that patient's follow-up responses without including names and other contact information. Upon completion of follow-up data collection, all contact information (names, addresses, and telephone numbers) will be destroyed.

The RTI evaluation study staff will use passwords to safeguard project directories and analysis files containing completed survey data to ensure that there is no inadvertent disclosure of study data. SBIRT staff also will be trained on handling sensitive data and the importance of confidentiality. All project staff will sign a confidentiality pledge. (See Attachment 10.) In addition, all studies involving human subjects will be reviewed and approved by RTI's Institutional Review Board (IRB) (Federal Wide Assurance Number 3331) and by grantee IRBs as necessary prior to study implementation. In keeping with 45 CFR 46, Protection of Human Subjects, the SBIRT procedures for data collection, consent, and data maintenance are formulated to protect respondents' rights and the confidentiality of information collected. Strict procedures will be followed for protecting the confidentiality of respondents' information and for obtaining their informed consent. The IRB-approved model informed consent in Attachment 8 meets all Federal requirements for informed consent documentation. This template will be customized by each grantee to obtain informed consent for participation in the study. Any necessary changes to the surveys will be reviewed by the RTI IRB.

Data from the SBIRT patient surveys will be kept strictly confidential in compliance with the Privacy Act of 1974 (5 U.S.C. 552a). The confidentiality of data records will be explained to all respondents during the consent process and in the consent forms.

Practitioner Survey: No follow-up interviews will be administered to the practitioners, and no contact information will be collected. The survey data collected will be anonymous. Demographics and educational background characteristics will be collected along with a randomly generated site identification number. In some situations, these characteristics might permit the practitioner respondents to be identified. Therefore, the same protocols and data protections used for the patient data will be used to ensure the confidentiality of practitioner respondents. Practitioners will be required to give verbal informed consent. (See Attachment 11.)

11. Questions of a Sensitive Nature

Patient Survey: The SBIRT cross-site patient surveys, by necessity, will collect sensitive information about substance abuse and mental health and other health and social risk factors because these are all outcomes of interest to SAMHSA. Sensitive information of this nature is always regarded as highly confidential, and confidentiality for clients in federally assisted treatment programs is assured through strict adherence to Federal Regulation 42 CFR, Part 2. The survey staff of the Cross-Site Evaluation Team will obtain consent for participation in the survey data collection. Respondents will be informed about the purpose of the data collection and that responding to all survey questions is voluntary. They will be assured that they may stop taking the survey at any time without forfeiting the cash incentive. In addition, specific assurances will be provided to respondents concerning the safety and protection of data collected from them.

Practitioner Survey: No sensitive information will be collected from the practitioners. The survey staff of the Cross-Site Evaluation Team will obtain verbal consent for participation in the survey data collection. Respondents will be informed about the purpose of the data collection and that responding to all survey questions is voluntary. In addition, specific assurances will be provided to respondents concerning the safety and protection of data collected from them. Respondents' names or other identifying information will not be collected.

12. Estimates of Annualized Hour Burden

Estimate the annualized hour burden of the collection of information from patients. The total patient sample size for the SBIRT cross-site data collection effort is estimated to be a maximum of 4,500 respondents aged 18 to 64. The baseline survey is expected to have a response rate of 80%, therefore resulting in 3,600 respondents completing the baseline survey. The 6-month follow-up survey is expected to have a response rate of 80% of the baseline sample, leaving 2,880 respondents with baseline and follow-up data. Exhibit 2 presents estimates of annualized burden based on preliminary testing. Although the average burden is calculated using the average time from testing, the time required to complete the surveys varies with patient characteristics, in particular substance use. The surveys were timed with a disproportionate number of hypothetical heavy substance users. The time to complete the surveys for the majority of patients will be significantly faster than the average. As evidence from the testing, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information the total estimated time to complete the baseline survey is 25 minutes. The 6-month followup survey adds 2 sections to the baseline survey and it is estimated that it will take 28 minutes to complete and the practitioner survey is estimated to take 24 minutes to complete.

Exhibit 2. Cross-Site Data Collection Burden for Patient and Practitioner Surveys

Instrument/Activity	Number of Respondents	Responses per Respondent	Hours per Response	Total Burden Hours	Hourly Wage	Total Respondent Cost[a]
Baseline data collection (Patients)	3,600	1	.42	1,512	$18	$27,216
6-month follow-up data collection (Patients)	2,880	1	.47	1,354	$18	$24,365
Patient Subtotal	3,600			2,866		$51,581
Practitioner survey	261	1	.40	104	$31	$3,224
TOTAL	3,861			**2,970**		**$54,805**

[a]Total respondent cost is calculated as hourly wage × time spent on survey × number of respondents.

Estimate the annualized hour burden of the collection of information from practitioners. The total practitioner sample size for the SBIRT cross-site data collection effort is estimated to be a maximum of 261 respondents (58 sites, 4 to 5 respondents in each site). Exhibit 2 presents estimates of annualized burden based on preliminary testing.

Estimate the annualized cost burden to the respondent for the collection of information from patients. There are no direct costs to respondents other than their time to participate in the study. The annual cost of the time respondents spend completing these surveys is $51,581 (number of total baseline patient respondent hours plus follow-up respondent hours × $18, the estimated average hourly wages for adults as published by the Bureau of Labor Statistics, 2004).

Estimate the annualized cost burden to the respondent for the collection of information from practitioners. There are no direct costs to respondents other than their time to participate in the study. The annual cost of the time respondents spend completing these surveys is $3,224 (number of practitioner respondent hours × $31, the estimated average hourly wages for individuals working in health-related occupations as published by the Bureau of Labor Statistics, 2004).

13. Estimates of Annualized Cost Burden to Respondents

There are no respondent costs for capital or start-up or for operation or maintenance.

14. Estimates of Annualized Cost to the Government

The estimated cost to the government for the cross-site data collection is $5,695,000. This includes $5 million for a 5-year contract for sampling, data collection, processing, reports, etc. and approximately $139,000 per year represents SAMHSA costs to manage/administrate the survey for 2% of one employee (GS-15). The annualized cost is approximately $1,139,000.

15. Changes in Burden

This is a new collection of information.

16. Time Schedule, Publications, and Analysis Plan

Time Schedule: Exhibit 3 outlines the key time points for the study and for the collection of information. The requested period also allows for training and start-up activities associated with the preparation for data collection.

Exhibit 3. Time Schedule for Entire Project

Activity	Time Schedule
Obtaining OMB approval for data collection	September 2006
Baseline data collection	3 months post OMB approval for 3 months
Six-month follow-up data collection	6 months post OMB approval for 3 months
Data analysis	Beginning one year post OMB approval
Dissemination of findings	Beginning 18 months post OMB approval through
Interim reports, manuscripts, final report	2009

Publications: The SBIRT cross-site evaluation is designed to produce knowledge about the implementation and impact of SBIRT models. It is therefore important to prepare and disseminate reports, concept papers, documents, and oral presentations that clearly and concisely present project results so that they can be appreciated by both technical and nontechnical audiences. The SBIRT Cross-Site Evaluation Team will:

- Produce rapid-turnaround analysis papers, briefs, and reports;
- Prepare and submit monthly technical progress reports and a final SBIRT Cross-Site Evaluation Team report;
- Prepare final cross-site findings report, including an executive summary;
- Deliver presentations at professional and federally sponsored conventions and meetings; and
- Disseminate reports and materials to entities inside and outside CSAT.

Analysis Plan: The outcome analysis centers on specific patient and practitioner questions found in Attachment 12. Specific analyses used to apply to these questions are explained in the remainder of this section.

Patient Survey: The patient outcome analysis will be primarily model-based and will be performed for both individual grantee populations and the total population pooled across grantees as appropriate. A case study approach will be used if the data are not sufficient to allow for valid pooling of data. To assess the overall impact of SBIRT services on patient-level outcomes, CSAT will use a generalized linear model (GLM) framework. The basic model is specified in the following general equation:

$$Y_{ijt} = f(\alpha + \beta POST_t + \delta TIME_{it} + \gamma CONTROL_{ijt}) + \varepsilon_{ijt}$$

where

Y_{ijt} is the outcome for individual i from grantee j at time t;
$f(\cdot)$ represents the linking function;
α, β, δ, and γ are coefficients to be estimated;
$POST_t$ is an indicator variable that equals 1 if the observation occurs at the 6-month follow-up;

$TIME_{it}$ is a vector of calendar time-related control variables (e.g., calendar year and indicators for quarters);
$CONTROL_{ijt}$ is a vector of grantee and individual characteristics and a set of site-specific indicators that may affect the outcome, including demographics and background characteristics such as those found in the NOMs; and
ε_{ijt} is the residual error term.

The primary coefficient of interest (β) measures the pre to post change in the outcome. That is, it quantifies the association between the treatment and the outcome. The model will be estimated separately for patients screening positive for BI, BT, and RT. In future years, depending on the quality of patient-level data, the analysis will include formal statistical hypothesis testing of the effects of individual components of SBIRT, such as the choice of screening instrument. In addition, with sufficient data, the model can be used to estimate the impact of SBIRT on other patient-level outcomes, including outcomes specified in the NOMs.

All model-based estimations will account for clustering at organizations within grantees. A variety of methods are available to account for this clustering, but in most cases CSAT proposes to use SUDAAN to appropriately account for the sampling design described in Section B.2. In this approach, a random error component is specified for each level of data in the analysis. The resulting variance structure of estimated parameters (including sample means and sample proportions) accounts for the clustering of observations. Attachment 13.1 is an illustrative sample table shell in which the model-based analysis results may be reported.

Analyses planned for the SBIRT cross-site evaluation also include descriptive analyses, such as tabulated results or graphs (e.g., histograms) for key outcomes. Each table will show cell estimates (means or proportions), sample sizes, and standard errors. As appropriate, findings will also be presented separately for key subgroups (e.g., males versus females, Hispanic versus non-Hispanic). Statistical significance of differences between subgroups will be assessed using *t*-tests (continuous outcomes) and x2 tests (categorical outcomes). Design effects, including sample weights, will be taken into account in computing cell estimates and their associated standard errors, as well as for related bivariate tests. Attachment 13.2 is an illustrative sample table shell in which the descriptive analyses may be reported.

Practitioner Survey: The analysis will be based primarily on descriptive statistics on service delivery unit type and practitioner characteristics and attitudes. The basic approach will use both a case study design and a pooling of data. In addition, with data from the practitioner survey, statistical modeling will be used, similar to that described for the patient-level analysis. Attachment 14 is a table shell in which results of the analysis of practitioner outcomes may be reported.

17. Display of Expiration Date

OMB approval expiration dates will be displayed on the opening screen of the CAPI surveys and on the project description handout that the patient receives.

18. Exceptions to Certification for Statement

There are no exceptions to the certification statement. The certifications are included in this submission.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Patient Survey: The targeted universe for the SBIRT evaluation patient survey is patients presenting for health care treatment in each participating grantee, with some exclusions that vary by grantee. Eligibility for the receipt of SBIRT services is limited to patients aged 18 to 64 who are not mentally or physically incapacitated and who are not currently in the custody of law enforcement officers. Based on estimates of patient flow from data collected by the grantees for GPRA reporting, the expected total number of patients who will be available and eligible during the data collection period is 13,397.

Practitioner Survey: Under the proposed sampling paradigm for obtaining patient-level information, all practitioners (e.g., physicians, health educators) in health care providers that deliver SBIRT services at the selected units are eligible to be surveyed. These include health educators, chemical dependency counselors, physicians, nursing staff, and other staff involved in the delivery of SBIRT services. Given that practitioners of the same type and at the same units tend to be highly homogeneous with respect to other characteristics, taking a census or selecting a large sample of practitioners would be both burdensome and provide no additional information. As a result, CSAT proposes to select a minimum of two practitioners of each type from each participating unit. Decisions to select more than a single type practitioner per unit will be based on the volume of patient flow per unit and per SBIRT component and on the ratio of patients per practitioner during the data collection period. Selecting a minimum of two practitioners per type and unit and adjusting for patient volume will provide an all-inclusive representative sample of practitioners for analytic purposes.

2. Information Collection Procedures

In order to ascertain and evaluate characteristics common to SBIRT outcomes across these multiprotocol, multipopulation programs, the sampling frame is composed of either a census or a probability-based sample of all service delivery units within each grantee. At each selected unit, baseline surveys will be conducted among eligible individuals seeking general health care services for a predetermined period. This length of data collection for each grantee has been optimized to either obtain sufficient sample or to minimize the number of respondents in high-volume grantees.

Exhibit 4 presents grantee-level information regarding the number of service delivery units, length of data collection, and expected volume of patient flow during the proposed data collection period. This stratified clustered sampling paradigm is designed to produce the most representative sample of eligible patients and facilitate the unbiased estimation of SBIRT intervention impact across the seven grantees, within the constraints of length of data collection, budget, and respondent burden. Given cost and burden constraints, sufficient sample sizes for

each grantee may not be available to produce grantee-specific estimates, although the data collection periods have been adjusted in an effort to optimize the grantees' respective sample sizes.

Exhibit 4. Grantee-Level Characteristics

Grantee	Available Service Delivery Units	Selected Service Delivery Units	Length of Data Collection (Weeks)	Expected Patient Volume[a]
Alaska	2	2	6	1,391
California	17	17	2	4,467
Illinois	5	5	4	2,094
New Mexico	27	20	6	1,339
Pennsylvania	1	1	4	1,241
Texas	8	8	4	1,821
Washington	9	5	4	1,044
Total	69	58		13,397

[a]Volume is based on monthly average data provided by GPRA, number of selected units, and length of data collection.

The sampling design will permit data to be pooled across all seven grantees for each SBIRT component: brief intervention (BI), brief treatment (BT), referral to treatment (RT), and screening and feedback (SF). Exhibit 5 presents the expected number of final respondents after the 6-month follow-up interview for each SBIRT component by grantee. Assumptions related to data collection include an 80% eligibility rate (20% of available patients will be surveyed by

Exhibit 5. Expected 6-Month Follow-up Interview Final Respondent Sample by Grantee and SBIRT Component

		SBIRT Component			
Grantee	Total	Brief Intervention	Brief Treatment	Referral to Treatment	Screening and Feedback
Alaska	369	64	12	43	250
California	589	250	52	37	250
Illinois	403	90	15	48	250
Texas	403	114	8	31	250
Washington	508	209	24	25	250
Pennsylvania	293	41	1	1	250
New Mexico	300	31	17	2	250
Total Respondents	2,865	799	129	187	1,750
Total Available Patients	13,397	1,719	261	373	11,044

GPRA), an 80% response rate at time of baseline survey, and a 20% loss of sample due to attrition at the 6-month follow-up interview. Additionally, even with the loss of sample due to eligibility, response, and attrition, a cap of 250 respondents was implemented for those high-volume SBIRT components in which the actual expected final respondent sample would have been cost prohibitive and provided no additional gain in precision.

Exhibit 6 presents the expected difference in outcomes from baseline to 6-month follow-up that would be considered significant at a two-sided 95% confidence level and with 80% power. Calculations for these detectable differences are based on the expected final respondent sample sizes per SBIRT component, the expected level of precision (i.e., standard deviation based on

weighted average across grantees provided by GPRA), and an overall conservative design effect of 4.0 to account for clustering, unequal sample sizes across grantees and SBIRT components, and general heterogeneity across grantees based on the respective protocols and populations served. Expected levels of precision are not available for the respondents who screened negative because outcome measures were not collected at the 6-month follow-up by GPRA. Sample size requirements for respondents who screen negative are based on representativeness of the target

Exhibit 6. Expected Significant Detectable Difference from Baseline to 6-Month Follow-Up

SBIRT Components	Outcome	Sample Size	Expected Precision (S.D.)	Detectable Difference
Brief Intervention	Days of drinking in past 30 days	799	6.96	1.38
	Days of drinking to intoxication (5+) in past 30 days		5.95	1.18
	Days of illegal drug use in past 30 days		6.71	1.33
Brief Treatment	Days of drinking in past 30 days	129	7.92	3.92
	Days of drinking to intoxication (5+) in past 30 days		8.00	3.96
	Days of illegal drug use in past 30 days		8.93	4.42
Referral to Treatment	Days of drinking in past 30 days	187	9.24	3.82
	Days of drinking to intoxication (5+) in past 30 days		9.21	3.81
	Days of illegal drug use in past 30 days		8.27	3.42

population (82.4% of all patient flow is expected to be screen negative), data collection cost constraints, and to preclude respondents who screened negative at baseline but had significant increases in substance use measures due to heavy substance use events (e.g., holidays and birthdays, during which substance use deviates substantially from individuals' average use) from exerting undue influence on the estimates.

Patient Survey: As described in Section A.6, the SBIRT patient survey will collect data from individuals at baseline and at 6-month follow-up. Data collection at the follow-up point is necessary to measure the short- and longer-term outcomes of the SBIRT programs implemented by the grantees. Because measuring these outcomes is one of the primary objectives of the SBIRT initiative, less frequent than semiannual data collection would greatly endanger the utility of the SBIRT initiative to all stakeholders.

Practitioner Survey: The practitioner survey will only be administered one time.

3. Methods to Maximize Response Rates

Patient Survey: The ability to gain the cooperation of potential respondents is key to the success of this endeavor. The SBIRT Cross-Site Evaluation Team anticipates an 80% to 85% response rate for the baseline patient survey, 15% to 20% attrition rate for the follow-up survey, and an 85% to 95% response rate for the practitioner survey. The evaluation team will employ several strategies to maintain high response rates:

- Use CAPI as the survey media.

- Stress the importance of the project as well as the evaluation team's commitment to respondent confidentiality.
- Train survey staff for handling sensitive information collection in a respectful manner.
- Develop bilingual survey in English and Spanish.
- Offer cash incentives for survey response.

To improve follow-up response rates, several strategies will be employed in addition to those stated above:

- Use CATI as the survey media, with CAPI being used for respondents who are unable to complete the survey via telephone.
- Collect detailed contact information, including alternate addresses and phone numbers and contact information of secondary sources who may know the respondents contact information at follow-up.
- Make interim phone calls to respondents at 3 months to maintain contact, update contact information, and remind respondents of the value of the study, confidentiality, and the cash incentive.

Practitioner Survey: To maximize initial response rates, the survey staff will follow protocols that will reduce the burden on practitioners. Planning and preparation in advance of the survey administration is crucial for these protocols. The protocols include proper timing and location of survey administration to accommodate the practitioners. The practitioners in selected health care provider sites will be informed, in advance, of the motivation and significance of the survey. Finally, the efficiency of the CAPI survey and the assurance of confidentiality will make survey completion more amenable to the practitioners.

4. Test of Procedures

Patient Survey: The SBIRT cross-site evaluation staff tested a pencil-and-paper version of the patient surveys with eight respondents and found that the baseline survey takes approximately 18 minutes to complete. The follow-up survey takes approximately 21 minutes. In addition, it takes 7 minutes to read and sign the informed consent and collect contact information. CSAT anticipates that the CAPI/CATI version will require less time to complete than the paper version. Because skip patterns are automatically embedded into the CAPI/CATI version, the participant will only view questions they need to respond to and less time will be spent following complicated skip pattern instructions. Also, the practice tests were performed for a variety of answer patterns, of which a disproportionate number were for a hypothetical heavy substance user. The majority of respondents will not be heavy users. The range of times from the baseline testing was 9 minutes to 28 minutes. The majority of respondents who are not heavy users will likely complete the baseline survey in less than the 18-minute average.

The patient surveys contain questions from the following four surveys and sets of measures:

- National Outcome Measures (NOMs)
- National Survey on Drug Use and Health (NSDUH)
- National Longitudinal Survey of Youth, 1979 (NLSY-79)
- National Vietnam Veterans Longitudinal Study (NVVLS)

In addition, three scales are included in the patient surveys. The Stanford Presenteeism Scale (SPS) (Koopman et al., 2002) measures the productivity of employees, which is often related to substance abuse. Its validity has been demonstrated among a broad cross-section of employee types (Turpin et al., 2004; Koopman et al., 2002; Kessler et al., 2004). The Patient Health Questionnaire (PHQ-8) (Spitzer et al., 1999) is included to gauge depression. It has been tested for validity (Spitzer et al., 1999; Lowe et al., 2004). The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (WHO, 2002) is the measure being used for alcohol and substance abuse. It has been shown to be sensitive to changes in alcohol and drug use behaviors (WHO ASSIST Working Group, 2002).

Practitioner Survey: The SBIRT cross-site evaluation staff tested a pencil-and-paper version of the practitioner survey with eight respondents and found that it takes approximately 19 minutes to complete. In addition, it takes 5 minutes to read and verbally acknowledge the informed consent for a total of 24 minutes. Like the patient surveys, it is likely that the CAPI version of the practitioner survey will take less time than the paper version.

The practitioner survey includes sets of questions that attempt to gauge barriers to implementation encountered by the practitioners and training received by the practitioners. These measures were used by Babor et al. (2005) in their study comparing two different implementation strategies for Cutting Back, a primary care alcohol screening and brief intervention program for hazardous and harmful drinkers. The survey includes a "Readiness to Change" scale for practitioners adopting SBIRT that was adapted from Rollnick et al (1992).

The evaluation team will thoroughly test the CAPI- and CATI-based surveys and all supporting computing systems before beginning data collection. In addition, data transmission, storage, and retrieval procedures and all supporting systems will be tested prior to data collection.

5. Statistical Consultants

As noted in Section A.8, the SBIRT Cross-Site Evaluation Team has consulted extensively with an expert panel that has reviewed and approved all data collection and analysis methodologies outlined in this package. They will also continue to provide expert advice throughout the course of the program. In addition, several in-house experts will be consulted throughout the program on various statistical aspects of the design, methodological issues, economic analysis, database management, and data analysis. Exhibit 7 provides details of these advisors.

Exhibit 7. Senior Advisors

Expert	Affiliation	Contact Information
Jeremy W. Bray, PhD Cross-Site Evaluation Director	Program Director Behavioral Health Economics Program RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-7003 Fax: 919-541-6683 E-mail: bray@rti.org
Georgiy Bobashev, PhD Advisor	Research Statistician Statistical Research Division RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-6161 Fax: 919-541-5966 E-mail: bobashev@rti.org
Gary A. Zarkin, PhD Advisor	Director Behavioral Health Research Division RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-5858 Fax: 919-541-6683 E-mail: gaz@rti.org
James Nonnemaker, PhD Advisor	Research Economist Public Health Economics and Policy Research RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-7064 Fax: 919-541-6683 E-mail: jnonnemaker@rti.org
Antonio Morgan-Lopez, PhD Advisor	Research Quantitative Psychologist Behavioral Health Research Division RTI International 3040 Cornwallis Road Research Triangle Park, NC 27709	Phone: 919-541-1246 Fax: 919-485-5555 E-mail: amorganlopez@rti.org

REFERENCES

Arndt, S.; Schultz, S.K.; Turvey, C.; and Petersen, A. Screening for Alcoholism in the Primary care Setting: Are We Talking to the Right People? *Journal of Family Practice* 51(1):41-46, 2002.

Babor, T.F. and J. Higgins-Biddle, D. 2000. "Alcohol Screening and Brief Intervention: Dissemination Strategies for Medical Practice and Public Health." *Addiction 95*(5):677-686.

Babor, T.F. 2002. "Is There A Need for an International Screening Test? The Middle East as a Case in Point". In: Isralowitz, R. and Rawson R. (eds). "Drug Problems, Cross-Cultural Policy and Program Development". pp.165-179. Westport CT: Auburn House.

Babor, T.F. 2004. "Brief Treatments for Canabis Dependence: Findings from a Randomized Multisite Trial". *Journal of Consulting and Clinical Psychology* 72(3):455-66.

Babor, T.F, J. Higgins-Biddle, D. Dauser, P. Higgins, and J. Burleson. 2005. "Alcohol Screening and Brief Intervention in Primary Care Settings: Implementation Models and Predictors." *Journal of Studies on Alcohol* 66(3):361-368.

Ballesteros, J., J.C. Duffy, I. Querejeta, J. Arino, and A. Gonzalez-Pinto. 2004. "Efficacy of Brief Interventions for Hazardous Drinkers in Primary Care: Systematic Review and Meta-Analyses." *Alcoholism: Clinical and Experimental Research* 28(4):608-618.

Barry, K.L. Consensus Panel Chair. 1999. "Brief Interventions and Brief Therapies for Substance Abuse". Treatment Improvement Protocol (TIP) Series 34. DHHS Publication no. (SMA) 99-3353. Rockville, MD: Center for Substance Abuse Treatment.

Bernstein, E., Bernstein, J., and Levenson, S. 1997. "Project ASSERT: An ED-based Intervention to Increase Access to Primary Care, Preventive Services and the Substance Abuse Treatment System". *Ann Emerg Med* 30:181-9.

Bloom, E.S. 1977 "An Approach for Casual Drug Users." NIDA Technical Paper. DHEW Publication No. (ADM) 77-533. Rockville, MD.

Blow, F.C. 1998 "Substance Abuse Among Older Adults." Treatment Improvement Protocol (TIP) Series 26. DHHS Publication No. (SMA) 98-3179. Rockville, MD: Center for Substance Abuse Treatment.

Breslin, C., Li, S., Sdao-Jarvie, K., Tupker, E., and Ittig-Deland, V. 2002. "Brief Treatment for Young Substance Abusers: A Pilot Study in an Addiction Treatment Setting". *Psychology of Addictive Behaviors*. 16(1): 10-16.

Broskowski, A. and Smith S. 2001. "Estimating the Cost for Preventive Services in Mental Health and Substance Abuse Under Managed Care". Substance Abuse and Mental Health Services Administration. SMA-02-3617R www.mentalhealth.org/publications/allpubs/SMA-02-3617R/appendix.asp

Church, O.M., and T.F. Babor. 1995. "Barriers and Breakthroughs: Substance Abuse Curricula in Nursing Education." *Journal of Nursing Education* 34(6):278-281.

D'Onofrio, G., L.C. Degutis, D.A. Fiellin, and M.V. Pantalon. June 2, 2000. "Screening and Brief Intervention for Alcohol Problems in the Emergency Department." In *Developing Best Practices for Emergency Care for the Alcohol-Impaired Patient: Recommendations from the National Conference*. Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration.

Degutis, L.C. 2003. "Need for Brief Interventions for Marijuana and Alcohol Use Related to Injuries". *Academic Emergency Medicine.* 10(1): 62-64.

Dennis, M., Babor, T.F., Roebuck, M.C., and Donaldson, J. 2002. "Changing the Focus: The Case for Recognizing and Treating Cannabis Use Disorders". *Addiction*. 97 Suppl. 1:4-15.

Department of Health and Human Services (DHHS), Public Health Service. 1990. "Alcohol-Related Mortality and Years of Potential Life Lost—United States, 1987." *Morbidity and Mortality Weekly Report* 39(11):173-178.

Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration. 1997. *A Guide to Substance Abuse Services for Primary Care Clinicians, Treatment Improvement Protocol (TIP) No. 24*. Rockville, MD: Center for Substance Abuse Treatment.

Fleming, M.F. 2002. "Screening, assessment, and intervention for substance use disorders in settings." In *Strategic Plan for Interdisciplinary Faculty Development: Arming the Nations' Health Professional Workforce for a New Approach to Substance Use Disorders.* Providence RI: Association for Medical Education and Research in Substance Abuse (AMERSA). www.projectmainstream.net/mainstream/supportdata/part1.pdf

Fleming, M.F. 2003. "Brief Interventions and the Treatment of Alcohol Use Disorders: Current evidence". In *Galanter, M. (ed). Recent Developments in Alcoholism.* Volume 16. Research on Alcoholism Treatment Methodology. Psychosocial Treatment, Selected Topics, Research Priorities. New York: Kluwer Academic Publishers, pp. 375-90.

Harwood, H., D. Fountain, and G. Livermore. 1998. *The Economic Costs of Alcohol and Drug Abuse in the United States, 1992*. Bethesda, MD: National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.

Heather, N. 2001. "Brief Interventions for Substance Use Disorders Other Than Alcohol." *Addiction.* 96(10):1511-2.

Kessler, R.C., M. Ames, P.A. Hymel, R. Loeppke, D.K. McKenas, D. Richling, P.E. Stang, and T.B. Üstün. 2004. "Using the WHO Health and Work Performance Questionnaire (HPQ) to Evaluate the Indirect Workplace Costs of Illness." *Journal of Occupational and Environmental Medicine* 46(Suppl 6):S23-S37.

Klitzner, M., Fisher, D., Stewart, K, and Gilbert, S. 1992. "Early Intervention for Adolescents". Princeton NJ: Robert Wood Johnson Foundation.

Koopman, C., K.R. Pelletier, J.F. Murray, C.E. Sharda, M. Berger, R.S. Turpin, P. Hackleman, P. Gibson, D.M. Holmes, and T. Bendel. 2002. "Stanford Presenteeism Scale: Health Status and Employee Productivity." *Journal of Occupational & Environmental Medicine* 44(1):14-20.

Lowe, B., K. Kroenke, W. Herzog, and K. Grafe. 2004. "Measuring Depression Outcome with a Brief Self-Report Instrument: Sensitivity to Change of the Patient Health Questionnaire (PHQ-9)." *Journal of Affective Disorders* 81(1):61-66.

Mangione, T.W., J. Howland, B. Amick, J. Cote, M. Lee, N. Bell, and S. Levine. 1999. "Employee Drinking Practices and Work Performance." *Journal of Studies on Alcohol* (March):261-270.

Modesto-Lowe, V., and A. Boornazian. 2000. "Screening and Brief Intervention in the Management of Early Problem Drinkers: Integration into Healthcare Settings." *Disease Management & Health Outcomes* 8(3):129-137.

Moyer, A., J. Finney, C. Swearingen, and P. Vergun. 2002. "Brief Interventions for Alcohol Problems: A Meta-Analytic Review of Controlled Investigations in Treatment-Seeking and Non-Treatment-Seeking Populations." *Addiction* 97:279-292.

Mrazek PJ and Haggerty RJ (eds). 1994. "Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research." Washington DC: *National Academy Press*.

Office of National Drug Control Policy (ONDCP). 2005. The national Drug Control Strategy. Washington DC: Office of National Drug Control Strategy.

Ohman-Strickland et al. In press. "Measuring Organizational Attributes of Primary Care Practices: Development of a New Instrument, A Study in the New Jersey Family Physicians Research Network." *HSR*.

Rice, D. 1993. "The Economic Cost of Alcohol Abuse and Alcohol Dependence: 1990." *Alcohol Health and Research World* 17(1):10-11.

Rice, D. 1999. "Economic Costs of Substance Abuse." 1995. *Proceedings of the Association of American Physicians* 111(2):119-125.

Roche, A.M.; Stubbs, J.M.; Sanson-Fisher, R.W.; and Saunders, J.B. A controlled trial of educational strategies to teach medical students brief intervention skills for alcohol problems. *Preventive Medicine* 26(1):78-85, 1997.

Rollnick, S., N. Heather, R. Gold, and W. Hall. 1992. "Development of a Short 'Readiness to Change' Questionnaire for Use in Brief, Opportunistic Interventions among Excessive Drinkers." *British Journal of Addiction* 87(5):743-754.

Saitz, R., N.J. Horton, L.M. Sullivan, M.A. Moskowitz, and J.H. Samet. 2003. "Addressing Alcohol Problems in Primary Care: A Cluster Randomized, Controlled Trial of a Systems Intervention. The Screening and Intervention in Primary Care (SIP) Study". *Annals of Internal Medicine* 138(5):372-382.

Spitzer, R.L., K. Kroenke, and J.B. Williams. 1999. "Validation and Utility of a Self-Report Version of the PRIME-MD: The PHQ Primary Care Study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire." *Journal of the American Medical Association* 282(18):1737-1744.

Turpin, R., R. Ozminkowski, C. Sharda, J. Collins, M. Berger, G. Billotti, C. Baase, M. Olson, and S. Nicholson. 2004. "Outcomes of a Population-based Asthma Management Program: Quality of Life, Absenteeism, and Utilization." *Journal of Occupational and Environmental Medicine* 46:1123-1133.

Bureau of Labor Statistics. National Compensation Survey. <http://data.bls.gov/PDQ/outside.jsp?survey=nc>. Accessed on Mar, 11, 2006.

World Health Organization (WHO) ASSIST Working Group. 2002. "The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): Development, Reliability and Feasibility." *Addiction* 97:1183-1194.

World Health Organization (WHO) Brief Intervention Study Group. 1996. "A Cross National Trial of Brief Intervention with Heavy Drinkers." *American Journal of Public Health* 86:948-955.

Wright, D., Bowman, K., Butler, D., & Eyerman, J. (2002). *Nonresponse Bias from the National Household Survey on Drug Abuse Incentive Experiment*. Paper presented at the Annual Meeting of the American Association for Public Opinion Research, St. Petersburg Beach, FL.

Zweben, A. and Fleming, M.F. 1999. "Brief Interventions for Alcohol and Drug Problems". In Tucker, JA, Donovan, DM and Marlatt, GA (EDS). "Changing Addictive Behavior: Bridging Clinical and Public Health Strategies". New York NY: Guilford Press. Pp. 251-282.

ATTACHMENTS

Attachment 1:	Authorizing Legislation
Attachment 2:	SAMHSA Substance Abuse Treatment Capacity Performance Goals
Attachment 3:	Baseline Patient Survey
Attachment 4:	Follow-Up Patient Survey
Attachment 5:	Practitioner Survey
Attachment 6:	Federal Register Notice
Attachment 7:	Project Description Handout
Attachment 8:	Patient Informed Consent
Attachment 9:	Network Security at RTI International
Attachment 10:	Confidentiality Notice
Attachment 11	Practitioner Informed Consent
Attachment 12	Outcome Evaluation Questions
Attachment 13	Table Shells – Model Based and Descriptive Results
Attachment 14:	Table Shell - Descriptive Results, Practitioner Outcomes