SUPPORTING STATEMENT FOR THE GOVERNMENT PERFORMANCE AND RESULTS ACT CLIENT/PARTICIPANT OUTCOME MEASURE

JUSTIFICATION

A1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ) is requesting approval from the Office of Management and Budget (OMB) for revisions to the previously approved instrument and data collection activities for the Government Performance and Results Act (GPRA) Center for Substance Abuse Treatment (CSAT) Client/Participant Outcome Measure (OMB No. 0930–0208) which expires on January 31, 2020. Specifically, CBHSQ is requesting approval to add 14 new questions to its existing GPRA instrument. Thirteen of these questions are intended for specific SAMHSA grant program(s) and one question on behavioral health diagnoses will be collected by all CSAT grantees using this instrument. Individual grantees will be responsible for responding to no more than four new questions (three program-specific questions in addition to the behavioral health diagnosis question).

This information is collected using a client-level instrument that provides SAMHSA the capacity to report on the performance and outcomes for all of its discretionary programs, including: demographic characteristics of individuals served; clinical characteristics of individuals served before, during, and after receipt of services; numbers of individuals served; and characteristics of services and activities provided. In order to be fully accountable for the spending of federal funds, SAMHSA requires all programs to collect and report data on all clients served to ensure program goals and objectives are being met. Data collected as part of this package will be used to monitor performance through the grant period and to ensure appropriate spending of federal funds.

Approval of this information collection will allow SAMHSA to continue to meet the Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

In order to carry out section 1105(a) (29) of the GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity. This plan must:

- a) Establish performance goals to define the level of performance to be achieved by a program activity;
- b) Express such goals in an objective, quantifiable, and measurable form;
- c) Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- d) Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;

- e) Provide a basis for comparing actual program results with the established performance goals; and
- f) Describe the means to be used to verify and validate measured values.

SAMHSA's legislative mandate is to increase access to high quality prevention and treatment services and to improve outcomes. Its mission is to reduce the impact of substance use and mental illness on our communities.

All SAMHSA's programs and activities are geared toward the achievement of goals related to reducing the impact of substance use and mental health disorders. GPRA performance monitoring is a collaborative and cooperative aspect of this process.

This request represents a first step in SAMHSA's efforts to improve its ability to assess the impact of its programs, and to use data collected from its discretionary grant portfolio to enhance grantee performance and to improve the lives of Americans with mental health and substance use disorders. To help accomplish these goals, SAMHSA is undertaking an effort to enhance and modernize its data collection efforts over the next two years. The current request seeks approval to revise the current data collection tools to: 1) add a small number of program-specific questions that will provide vital information on key grant outcomes; and, 2) add standardized International Statistical Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) diagnostic codes that will allow SAMHSA to identify who is receiving services, and whether clients with the highest level of need (e.g., individuals with serious mental illness, serious emotional disturbance, and substance use disorders) are improving following initiation of SAMHSA funded services. In fall 2018, SAMHSA plans to submit another request to OMB to make significant modifications to its data collection activities that will incorporate standardized, validated screening instruments to better assess program, grantee, and client outcomes.

A2. Purposes and Use of Information

SAMHSA uses this measure to report on the performance and outcomes of its discretionary services grant programs. The information is used by individuals at three different levels: the Assistant Secretary and SAMHSA staff, the Center administrators and Government Project Officers (GPOs), and grantees:

Assistant Secretary Level – The information is used to inform the Assistant Secretary for Mental Health and Substance Use of the performance and outcomes of the programs funded through the Agency. The performance is based on the goals of the grant program. This information serves as the basis of the annual GPRA report to Congress contained in the Justifications of Budget Estimates.

Center Level – In addition to providing information about the performance of the various programs, the information is used to monitor and manage individual grant projects within each program. The information is used by GPOs to identify program strengths and weaknesses, to provide an informed basis for providing technical assistance and other support to grantees, to inform funding decisions, and to identify potential issues for additional evaluation

Grantee Level – In addition to monitoring performance and outcomes, the grantee staff uses the information to improve the quality of treatment services provided to clients within their projects.

SAMHSA and its Centers will use the data for annual reporting required by GPRA to describe and understand changes in outcomes from baseline to follow-up to discharge. GPRA requires that SAMHSA's report for each fiscal year include actual results of performance monitoring for the three preceding fiscal years. The information collected through this revised data collection process allows SAMHSA to report on the results of performance and outcomes in a manner that is consistent with SAMHSA specific performance domains, and to assess the accountability and performance of its discretionary and formula grant programs.

Outcome data reflect the Agency's desire for consistency in data collected across the Agency. SAMHSA has implemented specific performance domains to assess the accountability and performance of its discretionary and formula grant programs. These domains represent SAMHSA CSAT's focus on the factors that contribute to the success of substance abuse treatment. The CSAT Client/Participant Outcome Measure will address the following performance domains:

- Abstinence from Drug / Alcohol Use
- Employment / Education
- Crime and Criminal Justice
- Family and Living Conditions
- Social Connectedness
- Social Consequences from Drug / Alcohol Use
- Access / Capacity
- Retention
- Recovery

Proposed Changes to Data Collection Tool

SAMHSA is proposing the revision of this data collection instrument (OMB No. 0903-0208) to improve performance monitoring and outcome measurement of its programs. The 13 questions to be added to this data collection instrument were developed by SAMHSA to understand specific outcomes of each grant program. Individual respondents will only be required to respond to a subset of these additional questions, with no respondent completing more than four new questions per response. Questions will be selected by SAMHSA based on the specific goals and characteristics of the grant program.

CBHSQ is now requesting approval to include the following 14 questions to its currently approved data collection:

Question	Item
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Number	
1	Behavioral Health Diagnoses - Please indicate patient's current behavioral health diagnoses using the International Statistical Classification of Diseases, 10 th revision- Clinical Modification (ICD-10-CM) codes listed below: (Select from list of Substance Use Disorder Diagnoses and Mental Health Diagnoses).
2	[For grantee follow-up and discharge only] Which of the following occurred for the client, subsequent to receiving treatment?a. Client was reunited with child (children)b. Client avoided out of home placement for child (children)c. None of the above
3	[For grantee] Please indicate the following: a. Was this client diagnosed with an opioid use disorder? (Yes/No) i. If yes, indicate which FDA-approved medication the client received for the treatment of opioid use disorder. (Methadone, Buprenorphine, Naltrexone, Extended-release naltrexone, Client did not receive an FDA-approved medication for opioid use disorder) 1. If client received an FDA-approved medication for opioid use disorder, indicate the number of days the client received medication. a. Was the client diagnosed with an alcohol use disorder? (Yes/No) i. If yes, indicate which FDA-approved medication the client received for alcohol use disorder. (Naltrexone, Extended-release Naltrexone, Disulfiram, Acamprosate, Client did not receive an FDA-approved medication for alcohol use disorder) 1. If client received an FDA-approved medication for alcohol use disorder, indicate the number of days the client received medication.
4	[For client at follow-up and discharge only] Did the [insert grantee name] help you obtain any of the following benefits? a. Private health insurance b. Medicaid c. SSI/SSDI d. TANF e. SNAP f. Other (please specify) g. None of the above
5	[For client at follow-up and discharge only] Have you achieved any of the following since you began receiving services or supports from [insert grantee name]? If yes, do you believe that the services you received from [insert grantee name] helped you with this achievement? a. Enrolled in school b. Enrolled in vocational training c. Currently employed

	d. Living in stable housing
6	[For client at follow-up and discharge only] Please indicate the degree to
	which you agree or disagree with the following statements (Strongly
	Disagree, Disagree, Undecided, Agree, Strongly Agree).
	a. Receiving treatment in a non-residential setting has enabled me to
	maintain parenting and family responsibilities while receiving
	treatment.
	b. As a result of treatment, I feel I now have the skills and supports to
	balance parenting and managing my recovery.
7	[For client follow-up and discharge only] Please indicate the degree to
	which you agree or disagree with the following statements (Strongly
	Disagree, Disagree, Undecided, Agree, Strongly Agree).
	a. Receiving treatment in a residential setting with my child
	(children) enabled me to focus on my treatment without the
	distractions of parenting and family responsibilities.
	b. As a result of treatment, I feel I now have the skills and supports to
	balance parenting and managing my recovery.
8	[For grantee] Please indicate which type of funding was/will be used to
	pay for the SBIRT services provided to this client. (Check all that apply):
	a. Current SAMHSA grant funding
	b. Other federal grant funding
	c. State funding
	d. Client's private insurance
	e. Medicaid/Medicare
9	f. Other (Specify) [For grantee at intake only] If the client screened positive for substance
3	misuse or substance use disorder, was the client assigned to the following
	types of services? [For grantee at follow-up and discharge only] Did the
	client receive the following types of services?
	a. Brief Intervention (Yes/No/Don't know)
	b. Brief Treatment (Yes/No/Don't know)
	c. Referral to Treatment (Yes/No/Don't know)
10	[For grantee] Did this client screen positive for a mental health disorder?
	If yes, were they referred for mental health services? If yes, did they
	receive mental health services?
	[For grantee] Did this client screen positive for a substance use disorder?
	If yes, were they referred for substance use services? If yes, did they
	receive substance use services?
11	[For client at follow-up only] Did the program provide the following:
	(Asked of client at follow up)
	a. HIV test – Yes/No
	i. If yes, the result was –
	Positive/Negative/Indeterminate/Don't know
	ii. If the result was Positive were you connected to
	treatment services? Yes/No

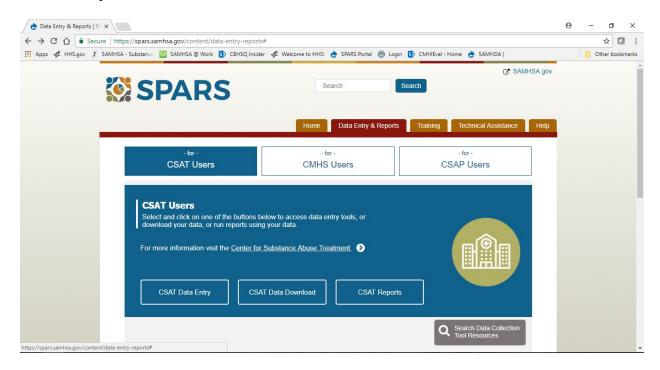
	b. Hepatitis B (HBV) test – Yes/No							
	i. If yes, the result was –							
	Positive/Negative/Indeterminate/Don't know							
	ii. If the result was Positive were you connected to							
	treatment services? Yes/No							
	c. Hepatitis C (HCV) test – Yes/No							
	i. If yes, the result was –							
	Positive/Negative/Indeterminate/Don't know							
	ii. If the result was Positive were you connected to							
	treatment services? Yes/No							
12	[For client at follow-up and discharge only] Indicate the degree to which							
	you agree or disagree with each of the following statements by using:							
	Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree, Not							
	Applicable							
	The use of technology accessed through (insert grantee or program name)							
	helped me							
	i. Communicate with my provider							
	ii. Reduce my substance use							
	iii. Manage my mental health symptoms							
	iv. Support my recovery							
13	[For client at follow-up and discharge only] To what extent has this							
	program helped improved your quality of life? (To a Great Extent,							
	Somewhat , Very Little , Not at All)							
14	For client] Please indicate the degree to which you agree or disagree with							
14	the following statement: Receiving community-based services through the							
	[insert grantee name] program has helped me to avoid further contact with							
	the police and the criminal justice system. (Strongly disagree to Strongly							
	agree)							
	ugice;							

All of CSAT's data collection activities are intended to promote the use of consistent measures among CSAT-funded grantees and contractors. These measures are a result of extensive examination and recommendations, using consistent criteria, by panels of staff, experts, and grantees. Wherever feasible, the measures are consistent with or build upon previous data development efforts within CSAT. These data collection activities are organized to reflect and support the domains specified for SAMHSA's programs providing direct services.

A3. Use of Improved Information Technology

Programs collect client information using a variety of methods, including paper-and-pencil and electronic methods. This project will not interfere with ongoing program collection operations that facilitate information collection at each site.

A web-based data collection and entry system, SAMHSA's Performance Accountability and Reporting System (SPARS), has been developed and is currently used and available to all programs for data collection. This web-based system allows for easy data entry, submission, and reporting to all those who have access to the system. Levels of access have been defined for users based on their authority and responsibilities regarding the data and reports. Access to the data and reports is limited to those individuals with a username and password. A screenshot of the data entry screen on SPARS is below:



A few programs submit their data electronically through an upload process. This facilitates the submission of data while avoiding duplication of the data entry process. Thus, programs that collect these data for other purposes are spared an additional collection burden.

Electronic submission of the data promotes enhanced data quality. With built-in data quality checks, easy access to data outputs and reports, users of the data can feel confident about the quality of the output. The electronic submission also promotes immediate access to the dataset. Once the data are put into the web-based system, it is available for access, review, and reporting by all those with access to the system from Center staff to the grantee staff.

A4. Efforts to Identify Duplication

The items collected are necessary in order to assess grantee performance. SAMHSA is promoting the use of consistent performance and outcomes measures across all programs; this effort will result in less overlap and duplication, and will substantially reduce the burden on grantees that results from data demands associated with individual programs.

A program-level review of current measures and methods of data collection was conducted to identify duplication of these data collection efforts. With the goal of creating questions for more

precise monitoring of grantee performance across the Center, existing questions were considered for use where appropriate. Each of the proposed questions was reviewed and approved by CSAT senior leadership as meeting the performance monitoring and management needs of individual programs and the Center.

SAMHSA will work closely with the grantees to identify whether other data are being collected by the grantee, which may be redundant to the GPRA instrument. When duplication is identified, SAMHSA and the grantees will identify a priority action plan to reduce the duplicative efforts, and streamline the data items to reduce client burden.

A5. Involvement of Small Entities

Individual grantees vary from small entities to large provider organizations. Every effort has been made to minimize the number of data items collected from all programs down to the least number of items necessary to accomplish the objectives described within and meet GPRA reporting requirements. Therefore, there is no significant impact to small entities.

A6. Consequences if Information Collected Less Frequently

Substance abuse treatment programs collect data at three time points: intake, six-month post intake, and discharge. Of note, the six-month post intake data collection may occur after the client has been discharged from the program. These times points are part of regular program activity.

These data collection points are generally accepted intervals for client assessment and the participants will be asked to respond to the items according to this schedule. The grantees for adolescent substance abuse treatment programs are required to collect information additionally at three months post-intake due to the transitory nature of adolescents. It is more difficult to locate adolescents than adults and, therefore, locating them more frequently and closer to their intake date should increase their follow-up rates. The data will be reported to SAMHSA on an annual basis in keeping with the GPRA requirements for annual reporting.

A7. Consistency with the Guidelines in 5 CFR1320.5(d)(2)

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

A8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on May 1, 2018 (83 FR 19075). No comments were received.

A9. Payment to Respondents_

Grantees are asked to budget for data collection in their grant applications and individual grantees are not prohibited from providing payments to their respondents for follow-up data

collection, which is customary practice in the field. If the grantees do provide payment for the follow-up, the maximum incentive is \$20.00 or the equivalent in coupons, transportation tokens, or other items per follow-up.

Survey research literature suggests that monetary incentives have a strong positive effect on response rates and no known adverse effect on reliability. In particular, substance abuse research has shown improved response rates when remuneration is offered to respondents. Substance abusers are typically a harder-to-reach population for whom out-of-pocket costs of participation (e.g., transportation, childcare) are significant barriers.

A10. Assurance of Confidentiality

The information from Grantees and all other potential respondents will be kept private through all points in the data collection and reporting processes. However, SAMHSA cannot ensure complete confidentiality of client data. SAMHSA will work with each grantee to prepare an impact assessment protocol. 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 least, the level of the grant/cooperative agreement-funding announcement.

SAMHSA has statutory authority to collect data under the GPRA (Public Law 1103(a), Title 31) and is subject to the Privacy Act for the protection of data. Federally assisted substance abuse treatment providers are subject to the federal regulations for alcohol and substance abuse patient records (42 CFR Part 2) (OMB No. 0930-0092) which govern the protection of patient identifying data. In some cases, these same providers meet the definition of a Health Insurance Portability and Accountability Act covered entity and are additionally subject to the Privacy Rule (45 CFR Parts 160 and 164) for the protection of individually identifiable data.

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 cooccurring 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 experiences with violence and trauma, criminal justice involvement, use of alcohol or other drugs, as well as issues of mental health. The data that will be submitted by each grantee will be based in large part on data that most of the programs are already routinely collecting. This primarily includes data on client demographics, substance abuse and treatment history, services received, and client outcomes. These issues are essential to the service/treatment context. Grant projects use informed consent forms as required and as viewed appropriate by their individual organizations. They also use the appropriate forms for minor/adolescent participants requiring parental approval. Client data are routinely collected and subject to the Federal Regulations on Human Subject Protection (45 CFR Part 46; OMB No. 0925-0404). Alcohol and drug abuse client records in federally supported programs are also protected by 42 CFR Part 2. The informed consent forms usually contain the following elements:

- Explanation of the purpose of the program or research.
- Expected duration of the subject's participation.
- Description of the procedures to be followed.
- Identification of any procedures that are experimental.
- Description of any reasonably foreseeable risks or discomforts to the subject.
- Disclosure of appropriate alternative procedures or courses of treatment.
- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- Contact names & phone numbers for participants to ask questions about program, participant rights, and injury.

A12. Estimates of Annualized Hour Burden

The time to complete the instruments is estimated in Table 1. These estimates are based on current funding and planned fiscal year 2018 notice of funding announcements and the number of consumers served in fiscal year 2017. The amount of time required to complete the new questions is based on an informal pilot and prior SAMHSA/CSAT experience in collecting similar data.

Table 1: Estimates of Annualized Hour Burden ¹ CSAT GPRA Client Outcome Measures for Discretionary Programs

SAMHSA Tool	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage ¹	Total Hour Cost
Baseline Interview Includes SBIRT Brief TX, Referral to TX, and Program-specific questions	179,668	1	179,668	0.60	107,801	\$21.23	\$2,288,611
Follow-Up Interview with Program-specific questions ²	143,734	1	143,734	0.60	86,240	\$21.23	\$1,830,884
Discharge Interview with Program-specific questions ³	93,427	1	93,427	0.60	56,056	\$21.23	\$1,190,073

¹ The hourly wage estimate is \$21.23 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21-1011 Substance Abuse and Behavioral Disorder Counselors = \$21.23/hr. as of March 2017. (http://www.bls.gov/oes/current/oes211011.htm. Accessed on February 7, 2018.)

Note: Numbers may not add to the totals due to rounding and some individual participants completing more than one form.

² It is estimated that 80% of baseline clients will complete this interview.

³ It is estimated that 52% of baseline clients will complete this interview.

SAMHSA Tool	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage	Total Hour Cost
SBIRT Program – Screening Only	594,192	1	594,192	0.13	77,245	\$21.23	\$1,639,911
SBIRT Program – Brief Intervention Only Baseline	111,411	1	111,411	.20	22,282	\$21.23	\$473,051
SBIRT Program – Brief Intervention Only Follow- Up ²	89,129	1	89,129	.20	17,826	\$21.23	\$378,442
SBIRT Program – Brief Intervention Only Discharge ³	57,934	1	57,934	.20	11,587	\$21.23	\$245,988
CSAT Total	885,271		1,269,495		379,037		\$8,046,959

The estimates in this table reflect the maximum annual burden for currently funded discretionary services programs. The number of clients served in following years is estimated to be the same assuming level funding of the discretionary programs, resulting in the same annual burden estimate for those years.

A13. Estimates of Annualized Cost Burden to Respondents

There are no capital or startup costs, nor are there any operation and maintenance costs.

A14. Estimates of Annualized Cost to the Government

The principal additional cost to the government for this project is the cost of a contract to collect the data from the various programs and to conduct analyses, which generate routine reports from the data collected. The reports examine baseline characteristics and changes between baseline, discharge, and each of the follow-up periods. It is the responsibility of the contractor to work with the GPO when preparing reports that combine the client services data with the annual reports of the project.

The estimated annualized cost for a contract for the GPRA mandate is \$7.2 million and the cost of one full-time equivalent staff (25% for the midpoint of one GS-14 \$25,899 and 75% for one GS-12 \$48,786) responsible for the CSAT data collection effort is approximately \$74,685/year.

A15. Changes in Burden

Currently, there are 338,748 burden hours in the OMB-approved inventory. SAMHSA is now requesting 379,037 hours. The program change is an increase of 40,289 hours due to the

addition of the 13 program-specific questions. The estimated time to complete the client interview with the revised tool has been increased from 31 minutes to 36 minutes.

A16. Time Schedule, Publication and Analysis Plans

Data for the annual GPRA plan/report are needed by SAMHSA by September of each year. The discretionary services program data are readily available through the web-based system. Data are provided for the most recently completed calendar year to SAMHSA in May in order to assure analysis in time for the annual GPRA report. The annual GPRA report must be submitted to the U.S. Department of Health and Human Services and to OMB by September and is included in the President's annual budget request which is released to the public February 1st. Data may be refined and added to the final Presidential budget request after the Department submits its initial GPRA report.

Analysis/Publication Plans

Client outcome data will be collected through the web site. Data will be used to report to Congress regarding the GPRA as specified in the SAMHSA Annual Justifications of Budget Estimates. The data might also be used for specific comparisons relative to the Office of National Drug Control Policy's National Drug Control Strategic Goals, especially for some of the secondary treatment outcomes (e.g., homelessness).

In the future, the indicators for clients served under these programs might be compared to similar indicators for clients served under block grant programs as a general indicator of whether the programs are doing better than "typical" services. This could be done for discretionary services programs as a group or for specific programs.

SAMHSA and each of its Centers specifically will use the data for annual reporting required by GPRA on the previously stated items, comparing baseline with discharge and follow-up data. The GPRA dataset will consist of each element coded into the reporting categories as seen in Attachment 1. These data are at the client record level. The SAMHSA GPRA performance and client outcome data will be aggregated at the following levels: Project/Grantee, Program/Division, and Activity. The analyses will be organized around SAMHSA's GPRA measures and the measures relating to the National Outcome Measures.

Baseline level analyses involves using frequency distributions and measures of central tendency to describe the populations across the GPRA client outcomes and by various demographic groups (e.g., gender, race, ethnicity, age, and level of education). The client will be followed longitudinally, with the GPRA client outcome items re-administered again at discharge and six months after baseline. The follow-up data also will be described using frequency distributions and measures of central tendency. Change will be addressed by comparing the discharge and follow-up measurements with baseline data for each client. The percent of clients showing the target changes will be calculated on each of the GPRA client outcome measures that are categorical. For continuous items, mean differences will be calculated. Tables will be constructed to describe the change across projects on client outcomes.

There will also be program-specific analysis of these data because each program may have unique programmatic and performance goals. The data items collected will be analyzed and presented in GPRA reports using basic descriptive statistics. On key outcomes (e.g., drug use, criminal involvement, and employment), the proportion of individuals showing improvement from baseline to discharge and follow-up (baseline to discharge, baseline to six months) will be calculated and aggregated at the program level (e.g., discretionary services). If deemed necessary for CSAT specific issues, the data will be examined at the individual activity level. The results will be examined for subpopulations of interest within individual activities (e.g., by age, by gender, by race/ethnicity, etc.).

A17. Display of Expiration Date

The expiration date for OMB approval will be displayed on all data collection instruments.

A18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.