

**STATE OPIOID RESPONSE (SOR) AND TRIBAL OPIOID RESPONSE (TOR)
PROGRAM DATA COLLECTION AND PERFORMANCE MEASUREMENT**

SUPPORTING STATEMENT

A. Justification

A.1 Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) is requesting approval from the Office of Management and Budget (OMB) for new data collection activities associated with the State Opioid Response (SOR) and Tribal Opioid Response (TOR) discretionary grant programs.

Listed below are the new data collection tools/instrument:

State Opioid Response/Tribal Opioid Response (SOR/TOR) Client-Level Data Collection Tool – Baseline (Attachment A)

State Opioid Response/Tribal Opioid Response (SOR/TOR) Client-Level Data Collection Tool – Follow-up (Attachment B)

State Opioid Response/Tribal Opioid Response (SOR/TOR) Program Instrument (Attachment C)

Information will be collected using a grantee-level (state/territory or tribal entity) tool and client-level tool that will provides CSAT with information about all SOR/TOR grantees, including: demographic information of clients served, services received (including use of Medication Assisted Treatment), behavioral health diagnoses, and substance use. In order to be fully accountable for the spending of federal funds, SAMHSA/CSAT requires all SOR/TOR grantees to collect and report data on clients served to ensure program goals and objectives are being met. Data collected as part of this package are used as a tool to monitor performance through the grant period. All data under this request will be collected electronically in SAMHSA's Performance and Accountability Reporting System (SPARS).

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.

The SOR/TOR programs and activities are geared toward the achievement of goals related to reducing the impact of opioid use and the opioid epidemic affecting the Nation. GPRA performance monitoring is a collaborative and cooperative aspect of this process.

A.2 Purpose and Use of Information

SAMHSA uses the performance measures to report on the performance of its discretionary services grant programs. The performance information is used by individuals at three different levels: the Assistant Secretary for Mental Health and Substance Use and SAMHSA staff, the Center administrators and government project officers, and grantees:

Assistant Secretary for Mental Health and Substance Use—The information is used to inform the administration of the performance of the SOR/TOR programs. The performance is based on the goals of the grant program and includes the National Outcome Measure (NOMs). 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 exploring the performance of the SOR/TOR programs, the information will be used to monitor and manage individual grant projects within each program. The information informs the government project officers of the program staff’s abilities to meet their individual goals.

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

Grantees will be required to collect client-level data from all individuals receiving opioid treatment and recovery services funded under the SOR/TOR grant programs. The CSAT SOR/TOR Client-level tool will address the following domains:

- Demographics
- Services Planned/Received
- Mental Health and Substance Use Diagnoses
- Medical Status
- Employment/Support Status

- Family/Social Relationships
- Substance Use
- Legal Status
- Psychiatric Status/Symptoms
- SOR/TOR Program Specific Questions

The CSAT SOR/TOR grantee-level tool will collect information on naloxone overdose reversal kits that were purchased and distributed using grant funds. This grantee-level information will be collected quarterly.

A.3 Use of Improved Information Technology

SOR/TOR grantees will collect client-level information using a variety of methods from paper and pencil to electronic methods. The SOR/TOR data collection will not interfere with ongoing program operations that facilitate information collection at each site as state/territories and tribal entity are already using collecting and reporting program data as a component of other SAMHSA grants.

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 entered 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.

A.4 Efforts to Avoid Duplication

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

Further, states will not be required to report SOR/TOR admissions and discharges as part of SAMHSA's Treatment Episode Data Set (TEDS) by SAMHSA, but state law may require them to do so. However, states will be encouraged to report all of the SUD treatment episodes for which they are able in an accurate manner.

A.5 Involvement of Small Businesses

Individual grantees are likely to vary from small entities to large provider organizations. Every effort has been made to minimize the number of data items collected from programs and sub-recipients to accomplish objectives of the SOR/TOR grant program and to meet GPRRA reporting requirements.

A.6 Consequences if Information Collected Less Frequently

SOR/TOR grant programs will collect data at four time points: intake, three months post intake, six months post intake, and discharge. The post-intake data collections may occur after the client

has been discharged from the program. These times points are part of regular program activity. If the data is collected less frequently, the ability to determine changes in client services and substance use will be difficult to ascertain.

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 data will be reported by SAMHSA on an annual basis in keeping with the GPRA requirements for annual reporting.

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

The data collection efforts will be consistent with the guidelines at 5 CFR 1320.5(d)(2).

A.8 Consultation Outside the Agency

As required by 5 CFR 1320.8(d), the 60-Day FRN was published in the *Federal Register* on October 4, 2018 (83 FR 50116). Twenty-eight comments were received from the 60-Day Notice (Attachment D). Attachment E are SMAHSA's responses to the comments.

A.9 Payment to Respondents

According to the SOR and TOR funding opportunity announcements (FOAs), grant funds cannot be used to "make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services" however, "[a] recipient or treatment or prevention provider may provide up to \$30 non-cash incentive to individuals to participate in required data collection follow up. This amount may be paid for participation in each required follow up interview."

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, child care) are significant barriers.

A.10 Assurance of Confidentiality

The information from SOR/TOR 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. All data will be closely safeguarded, and no institutional or individual identifiers will be used in reports. Only aggregated data will be reported.

SAMHSA has statutory authority to collect data under the Government Performance and Results Act (Public Law 1103(a), Title 31) and is subject to the Privacy Act for the protection of data. Federally assisted substance abuse treatment providers are subject to the federal regulations for alcohol and substance abuse patient records (42 CFR Part 2) which govern the protection of patient identifying data. In some cases, these same providers meet the definition of a HIPAA covered entity and are additionally subject to the Privacy Rule (45 CFR Parts 160 and 164) for the protection of individually identifiable data.

Health information data protection standards are taken to protect the information shared. The information is collected using multi-factor authentication and is stored in a Federal Information Security Modernization Act moderate compliant system that has an up to date Authority to Operate.

A.11 Questions of a Sensitive Nature

SAMHSA's mission is to improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for substance abuse and mental illnesses, including co-occurring disorders, in order to improve health and reduce illness, death, disability, and cost to society. In carrying out this mission it is necessary for service providers to collect sensitive items such as 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 SOR/TOR grantee will be based in large part on data that most of the programs are likely already routinely collecting. This primarily includes data on client demographics, substance use and treatment history, services received, and client outcomes. 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). 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.

A.12 Estimates of Annualized Hour Burden

Table 1 shows the estimated annualized burden hours for the respondents' time to participate in each data collection activity. The estimated number of clients participating in this data collection is based on the number of clients served by the State Targeted Response grant program in fiscal year 2018. Across the instruments, the total burden is estimated to be 401,788 hours. The total cost burden is estimated to be \$8,992,018.

Table 1. Estimate of Annualized Hour Burden for SOR/TOR Grantees

SAMHSA Data Collection	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage¹	Total Wage Cost
Grantee-Level Instrument	359	4	1,436	.17	244	\$22.38	\$5,463
Client-Level Instrument: Baseline Interview	165,000	1	165,000	.78	128,700	\$22.38	\$2,880,306
Client-Level Instrument: Follow-up Interview ²	132,000	2	264,000	.78	205,920	\$22.38	\$4,608,490
Client-Level Instrument: Discharge Interview ³	85,800	1	85,800	.78	66,924	\$22.38	\$1,497,759
CSAT Total	165,359		516,236		401,788		\$8,992,018

Notes:

The hourly wage estimate is \$22.38 based on the Occupational Employment and Wages, May 2017 Mean Hourly Wage Rate for 21-1018 Substance Abuse, Behavioral Disorder, and Mental Health Counselors as of September 2018 (<https://www.bls.gov/oes/current/oes211018.htm>) (Accessed on September 14, 2018).

² It is estimated that 80% of baseline clients will complete the three month and six month follow-up interviews.

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

A.13 Estimates of Annualized Respondent Capital and Maintenance Costs

There are neither capital nor startup costs, nor are there any operations or maintenance costs.

A.14 Estimates of Annualized Cost to the Federal Government

SAMHSA has planned and allocated resources for the management, processing, and use of the collected information in a manner that will enhance its utility to the federal government, as well as award recipients. The SPARS contract modification to cover the task order expansion of the current data collection system accommodating this data collection is approximately \$500,000. It is estimated that one full-time equivalent federal staff will be involved for 15% of their time, at an estimated annualized cost of \$15,000 to the government. The total estimated average cost to the government for year one is \$515,000, and \$15,000 for year two.

¹ The hourly wage estimate is \$20.64 based on the Occupational Employment and Wages, March 2016 Mean Hourly Wage Rate for 21-1011 Substance Abuse and Behavioral Disorder Counselors = \$20.64/hr. as of March, 2016. (<http://www.bls.gov/oes/current/oes211011.htm>) (Accessed on July 28, 2016).

² It is estimated that 80% of baseline clients will complete the 3 month and 6 month interview.

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

The annualized cost to the government is \$265,000.

A.15 Change in Burden

This is a new data collection.

A.16 Time Schedule, Publication and Analysis Plan

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 SPARS web-based system. The annual GPRA report must be submitted to the U.S. Department of Health and Human Services (the Department) 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.

Client outcome data will be collected through the SPARS web site. Data will be used to report to Congress regarding the GPRA as specified in the SAMHSA Annual Justifications of Budget Estimates. Program data will also be collected in SPARS.

SAMHSA and each of its Centers 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 client outcome data will be aggregated at the following levels: Grantee, and Activity. The analysis will be organized around SAMHSA's GPRA measures. The program data set will consist of each element coded into the reporting categories as seen in Attachment 2.

Baseline level analysis involves using frequency distributions and measures of central tendency to describe the populations across the GPRA clients and by various demographic groups (e.g., gender, race, ethnicity, diagnosis, age, and level of education). The client will be followed longitudinally, with the GPRA client outcome items re-administered again at discharge, three months 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.

Occasionally, the results will be examined for subpopulations of interest within individual activities (e.g., by age or by gender). Program level data will also be analyzed using frequency distributions and measures of central tendency as relevant.

A.17 Display of Expiration Date

The OMB expiration date will be displayed.

A.18 Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.