**SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment**

Supporting Statement A

**Check off which applies:**

[x]  New

[ ]  Revision

[ ]  Reinstatement with Change

[ ]  Reinstatement without Change

[ ]  Extension

[ ]  Emergency

[ ]  Existing

1. **JUSTIFICATION**
2. **Circumstances Making the Collection of Information Necessary**

Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a generic clearance for purposes of conducting qualitative research to gain a better understanding of emerging substance use and mental health policy issues, improve the development and quality of instruments, and to ensure SAMHSA leadership, centers and offices have recent data and information to inform program and policy decision-making. We seek to obtain OMB approval of a generic clearance to collect qualitative data on SAMHSA programs and policy issues. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield results that can be generalized beyond the population of study.

This collection of information is necessary to enable SAMHSA to receive feedback in an efficient, timely manner, in accordance with our mission to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes. SAMHSA is the agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders, and their families. It’s mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.  SAMHSA pursues this mission by providing grant funding opportunities and guidance to states and territories, as well as tribal and local communities; technical assistance to grantees and practitioners; publishing and sharing resources for individuals and family members seeking information on prevention, harm reduction, treatment and recovery; collecting, analyzing, and sharing behavioral health data; collaborating with other Federal agencies to evaluate programs and improve policies; and raising awareness of available resources through educational messaging campaigns and events.  Integral to this role, SAMHSA conducts qualitative research and evaluation studies, develops policy analyses, and estimates the cost and benefits of policy alternatives for SAMHSA related programs.

Qualitative research and assessment are the main objectives of the activities included in this clearance. The goal of establishing the SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment is to help public health officials, policymakers, community practitioners, and the public to understand mental health and substance use trends and how they are evolving; inform the development and implementation of targeted evidence-based interventions; focus resources where they are needed most; and evaluate the success of programs and policies. A key objective is to decrease the burden on stakeholders while expanding and improving data collection, analysis, evaluation, and dissemination. To achieve this objective, SAMHSA is streamlining and modernizing data collection efforts, while also coordinating evaluation across the agency to ensure funding and policies are data driven. Additionally, the agency is utilizing rigorous evaluation and analytical processes that are in alignment with the Foundations for Evidence-Based Policymaking Act of 2018. SAMHSA, using robust methods to collect, analyze, and report valid, reliable, trustworthy, and protected data, is key to improving and impacting behavioral health treatment, prevention, and recovery for communities most in need. By using rigorous methods, and improving the quality and completeness of program data, data can be disaggregated across different population groups to assess disparities within the behavioral health care system. SAMHSA’s vision will be accomplished by better leveraging optimal data to inform the agency’s policies and programs. The participants will include grant recipients, policy experts; national, state, and local health representatives; human service, and healthcare providers; and representatives of other health organizations.

1. **Purpose and Use of the Information Collection**

The purpose is to obtain broad and diverse perspectives on public health, human service, and health care issues to understand emerging issues, promising practices by innovative programs or organizations funded by SAMHSA. The data and information collected under this clearance will be published only if it is of methodological interest or if analysis suggest more study is necessary.

SAMHSA will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current programs, policies, and services. Under this clearance a variety of qualitative methods will be used, and the exact nature of the questions and samples is currently undetermined, and SAMHSA expects that they will include but not be limited to issues related to fully integrating behavioral health services and supports within all health care programs and systems; developing a well-trained, diverse, and culturally competent workforce; reducing incidence, prevalence, and mortality related to overdose and suicide; and providing the resources needed to develop, support, promote, and sustain resilience in children, youth, and families. The qualitative methods employed will vary based on the issue being examined. The information collected will provide insights into stakeholder perceptions, experiences and expectations; provide an early warning or serve as a barometer of substance use and mental health policy issues; or focus attention on areas where communication, training or changes in operations might improve delivery of services or program implementation. These collections will allow for ongoing, collaborative and actionable communications between SAMHSA and its internal and external stakeholders. SAMHSA will use this mechanism to improve our understanding of specific substance use and mental health issues and in targeted populations that drive further research or analysis.

SAMHSA will only submit a collection for approval under this generic clearance if it meets the following conditions:

* Information gathered will be used internally for generating and identifying policy issues and research gaps to ensure successful implementation of SAMHSA programs. Some information may not be for release outside of the agency, and if information is released, procedures outlined in Question 16 will be followed in accordance with HHS policy;
* Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the broader population;
* The collections are voluntary;
* The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the federal government;
* The collections do not raise issues of concern to other federal agencies;
* Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
* With the exception of information needed to provide renumeration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

If these conditions are not met, SAMHSA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form will be submitted to OMB along with supporting documentation (e.g., a copy of the focus group guide). OMB will respond to the submission with questions or approval within 14 business days, or as appropriate given the nature of the submission.

The types of collections that this generic clearance covers include, but are not limited to:

* Interviews
* Small discussion groups
* Focus Groups of stakeholders
* Questionnaires
* Other qualitative methods: other qualitative methods that SAMHSA typically uses such as, document studies, performance assessments, and case studies.

SAMHSA has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

1. **Consideration Given to Information Technology**

SAMHSA does its best to ensure we are requiring the least amount of burden when collecting information from the public. To the extent possible, we always strive to collect information electronically and/or use online collaboration tools to reduce burden.

1. **Duplication of Information**

SAMHSA collaborates and coordinates routinely with all parts of HHS and other federal agencies. We do our best to ensure no similar data are gathered or maintained by other parts of HHS or are available from other sources known to us. To the extent possible, SAMHSA collaborates with internal and external partners to ensure there is not duplication of information collected.

This information collection does not duplicate any other qualitative research methods being conducted by SAMHSA or at HHS in general. SAMHSA typically looks at cross-cutting issues that may involve several agencies within HHS to provide a departmental view and coordination. This clearance will improve the quality of SAMHSA’s policy research and assessment as well as providing a more efficient means for conducting more rigorous qualitative policy research and assessment. To the maximum extent possible, we will make use of previous information by reviewing results of previous qualitative research projects on relevant policy issues before we attempt to revise interview guides, questionnaires, and other tools using additional field work sought under this clearance.

1. **Reducing the Burden on Small Entities**

Small business or other small entities may be involved in these efforts but SAMHSA will minimize the burden of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments whenever possible.

1. **Consequences of Not Conducting Collection**

This clearance involves the use of qualitative research to inform policy research and assessments for dynamic public health, human service, and healthcare issues, changing trends in population health, and new health threats. If we do not continue this mechanism, SAMHSA will be limited in its ability to solicit feedback from broad and diverse policy experts and stakeholders, impacting our ability to provide up-to-date information from external stakeholders to SAMHSA leadership.

1. **Special Circumstances**

There are no special circumstances. The information collected will be voluntary and will not be generalizable.

1. **Consultations with Persons Outside the Agency**

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment was published in the *Federal Register* on August 10, 2023, (88 FR 54343). No comments were received.

1. **Payment or Gift**

SAMHSA will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback. If it becomes evident that remuneration is necessary, SAMHSA will provide $40 or less per respondent for in-person information collection, SAMHSA will include a statement to this effect and any other associated documentation as necessary in information collection requests under this mechanism. If evidence suggests that it is necessary to provide remuneration in excess of $40 per respondent, SAMHSA will provide a statement to this effect and will provide justification in the form of empirical evidence that the specified remuneration is necessary.

1. **Confidentiality**

SAMHSA does not anticipate the Privacy Act will apply to any of our data collections under this generic mechanism. If the Privacy Act applies to a collection, SAMHSA will provide a Privacy Act statement, SORN, or any other associated documentation as necessary. If a confidentiality pledge is deemed useful and feasible, the Agency will include a pledge of confidentiality that is supported by authority established in statute or regulation, that is supported by disclosure and data security policies that are consistent with the pledge, and that does not unnecessarily impede sharing of data with other agencies for compatible confidential use. If the agency includes a pledge of confidentiality, it will include a citation for the statute or regulation supporting the pledge. Most of the information collections under this mechanism have not collected personally identifiable information or information of a personal or sensitive nature. One should state that, “Data will be kept private to the extent allowed by law.”

1. **Sensitive Nature**

No questions will be asked that are of a personal or sensitive nature.

1. **Burden of Information Collection**

A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (15,000) are based on the number of collections we expect to conduct over the requested period for this clearance. The burden estimates were calculated based on the amount of IC submissions to the 0930-0393 Fast Track Generic Clearance for the Collection of Qualitative Feedback on the Substance Abuse and Mental Health Services Administration (SAMHSA) Service Delivery that are ineligible for OMB approval under it. This Generic information collection will provide a viable replacement option. Internal assessments of projected IC submission over the next three years estimate the burden hours for this information collection to be approximately half that of the 0930-0393 Fast Track Generic Clearance for the Collection of Qualitative Feedback on the Substance Abuse and Mental Health Services Administration (SAMHSA) Service Delivery.

Estimated Annualized Burden Table

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of respondent | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
| SAMHSA internal and external stakeholders | 15,000 | 1 | 1 | 15,000 |

1. **Costs to Respondents**

No costs are anticipated.

1. **Costs to Federal Government**

The anticipated cost to the federal government is approximately $600,000 annually, for a total of $1.8 million over the period of three years. These costs are comprised of: operational expenses (e.g., equipment, overhead, printing, and support staff), contractor payments and any other expense that is necessary to collect the information approved under this generic clearance.

1. **Reason for Change**

This is a request for a new information collection.

1. **Tabulation of Results, Schedule, Analysis Plans**

Information collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings may be disseminated when appropriate, strictly following the HHS "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitation of the qualitative results discussed above. SAMHSA may also receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests), and we will comply with those requests as appropriate.

1. **Display of OMB Approval Date**

We are requesting no exemption.

1. **Exceptions to Certification for Paperwork Reduction Act Submissions**

These activities comply with the requirements in 5 CFR 1320.9.