

Center for Behavior Health Quality and Statistics (CBHSQ) National Survey on Drug Use and Health (NSDUH)

SUPPORTING STATEMENT

Check off which applies:

- ☐ New
- ☒ Revision
- ☐ Reinstatement with Change
- ☐ Reinstatement without Change
- ☐ Extension
- ☐ Emergency
- ☐ Existing

A. JUSTIFICATION

1. Circumstances of Information Collection

Overview

NSDUH Main Study:

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for a revision to the National Survey on Drug Use and Health (NSDUH). The survey is sponsored by SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) and approved under OMB No. 0930-0110. The data collection is a national survey of the U.S. civilian, non-institutionalized population aged 12 or older. This survey is paramount in meeting a critical objective of SAMHSA's mission—to maintain current data on the incidence and prevalence of substance use and mental health problems in the United States. NSDUH has been conducted on a periodic basis from 1971 to 1988, and annually since 1990.

NSDUH is authorized by Section 505 of the Public Health Service Act (42 USC 290aa4 – Data Collection). Section 505 specifically authorizes annual data collection for monitoring the incidence and prevalence of illicit substance use and mental health problems, as well as the abuse of licit substances in the U.S. population.

Information collected through NSDUH has multiple applications, including 1) advancing the study of the epidemiology of substance use and mental health; 2) monitoring substance use and mental health trends and patterns; 3) identifying licit and illicit substances being used and abused (including those causing/contributing to medical, psychological, or social problems requiring emergency medical care or rehabilitation); 4) advancing the study of the use of health care resources for treatment of substance use and mental health problems; and 5) assisting federal, state and local agencies in the allocation of resources, and the proper design and implementation of substance use prevention, treatment, and rehabilitation programs.

The NSDUH will continue to use a sample design which provides data at both the national level and the state level. The survey's sample design includes targets to yield 4,560 completed interviews in California; 3,300 completed interviews each in Texas, New York, and Florida; 2,400 completed interviews each in Illinois, Pennsylvania, Ohio, and Michigan; 1,500 completed interviews each in Georgia, North Carolina, New Jersey, and Virginia; 967 completed interviews in Hawaii; and 960 completed interviews in each of the remaining 37 states and the District of Columbia. This approach will ensure a sufficient sample in every state to support either small area estimation (SAE) or direct estimation methods, while at the same time maintaining efficiency for national estimates.

The sample design will also include the same age group allocation implemented since the 2014 survey. To accurately estimate drug use and related mental health measures among the aging drug use population, the NSDUH sample will be allocated to age groups as follows: 25 percent 12 to 17, 25 percent 18 to 25, 15 percent 26 to 34, 20 percent 35 to 49, and 15 percent 50 or older.

Like previous NSDUHs, a hybrid address-based sampling (ABS) design will be implemented. ABS refers to the sampling of residential addresses from a list based on the U.S. Postal Service's Computerized Delivery Sequence file. In areas with high expected ABS coverage, the ABS frame will be used. In all other areas, traditional field enumeration will be used to construct the dwelling unit frames.

NSDUH will continue to employ a mix of in-person and web-based modes of administration, with the mode chosen by the respondent. Regardless of mode, the content of the interview questionnaire administered to respondents is identical and will be combined for analysis and reporting.

Questionnaire Changes

CBHSQ must also periodically update aspects of the NSDUH to reflect changing substance use and mental health issues and to continue producing current data. For the 2025 NSDUH the following changes from 2024 are planned:

1. updating the Hallucinogens Module to include follow-up questions for each hallucinogen;
2. adding three questions to the Health Module to measure sleep disorders (SLPFALL, SLPSTAY, and SLPMED) for adult respondents;
3. adding an introduction screen and two questions to the Health Module to measure chronic pain (PAININT, PAINPM and PAINLIM) for adult respondents;
4. adding two questions to the Youth Experiences Module to measure non-suicidal self-harm (SFHRMPY and SFHRMNUM);
5. removing the Prior Substance Use Module to lower respondent burden; and
6. removing 87 questions across nine modules for questionnaire clean-up reasons.

Overall, these changes are anticipated to reduce respondent burden and produce more up-to-date data.

The revisions to the Hallucinogens module will allow the 2025 NSDUH to collect more detailed information about a wider range of hallucinogens to better meet data users'

needs. The new questions measuring sleep disorders, chronic pain, and non-suicidal self-harm were added because the NSDUH did not previously include these items and they are of growing interest to data users. All removed questions, including the entire Prior Substance Use Module, were determined to be of low or no analytic value to CBHSQ. Removing these questions will allow room to add questions that are more useful to CBHSQ and relevant to data users in the future.

For further reference, a detailed summary of all specific NSDUH questionnaire changes for 2025 is included on page 1 of **Attachment N**, In-Person CAI Questionnaire.

Updated Lead Letter

In addition, CBHSQ is proposing the use of an updated Lead Letter (**Attachment A**) for the 2025 NSDUH. The updated letter is the result of the NSDUH Lead Letter Focus Groups (OMB No. 0930-0290) conducted in 2023, in which 58 participants aged 18 or older provided feedback on the overall appearance and specific elements of the current (i.e., 2023) version versus an alternative version of the Lead Letter. The objective of the focus groups were to improve the clarity and readability of the letter for all members of the target population, including making it as easy as possible for members of sample dwelling units to determine how they can participate in the study. An overview of the methodology, recruitment procedures, participant selection, and a summary of findings from the focus groups can be found in the attached **Lead Letter Focus Group Addendum**. Based on the focus group findings, a hybrid Lead Letter (i.e., the proposed 2025 letter) was developed in 2024 that (1) retained key elements of the 2023 letter to maintain legitimacy and (2) added a few design elements from the alternative letter preferred by focus group participants. The updated Lead Letter for 2025 includes the following design changes:

- different font (Source Sans Pro rather than Times New Roman);
- fewer words and less bolding;
- more appealing blue color throughout the letter;
- higher focus on how to participate:
 - placed a box around the instructions for participating (online and in-person) to help catch the reader's attention,
 - added numbered steps for participating online,
 - included a line separating online from in-person participation,
 - moved quick response (QR) code from the bottom of the letter to inside the box next to the instructions for participating online;
- added headers to help (e.g., "Privacy") the reader locate information; and
- simplified the footnotes.

Exploratory Pilot Testing in the U.S. Territories:

The U.S. Congress is committed to improving mental health and substance use care for people living in the U.S. Territories. To align with that initiative, SAMHSA is interested

in expanding NSDUH data collection to include U.S. territories. This will involve conducting several pilot tests and implementing a phased approach before expanding data collection full scale into the U.S. Territories. The initial phase will explore logistical considerations in Puerto Rico and in the U.S. Virgin Islands, followed by various data collection pilot efforts that will assess the ease or difficulty with recruiting field staff, potential travel difficulties due to terrain, internet reliability, differences in address conventions, language dialect differences, and differences in demographic characteristics. The results of the pilot testing will provide SAMHSA with insights into the feasibility of successfully conducting full-scale data collection in future NSDUH surveys.

Data collection pilot efforts in Puerto Rico began in 2023 and will continue through 2025; pilot efforts in the U.S. Virgin Islands will be conducted in 2024.

Mental Illness Calibration Study:

Embedded within 2023 and 2024 NSDUH main study data collection, the Mental Illness Calibration Study (MICS) is being conducted to recalibrate the estimates of serious mental illness (SMI) for the NSDUH using the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition (DSM-5) criteria published by the American Psychiatric Association (APA). The DSM is the manual used by clinicians and researchers to diagnose and classify mental disorders, including SMI. The 2023 and 2024 MICS will be sampled from the main study NSDUH using completed mental health items as screeners. Adults aged 18 years and older will be recruited to complete a 60-minute clinical interview focused on mental disorder symptoms. The goal is to conduct at least 2,000 follow-up clinical interviews each year. All clinical interviews will be conducted in English. Currently, CBHSQ does not plan to continue the MICS beyond 2024.

The current NSDUH SMI estimates were developed under the 2008 – 2012 Mental Health Surveillance Study (MHSS) and reflect DSM-IV criteria. In the intervening years, the DSM was updated, and it is important to update the NSDUH mental illness estimates to reflect current criteria. A similar methodological approach was used for the MHSS, applying similar sampling and weighting algorithms. Using similar sampling, study instrumentation, and statistical modeling procedures between the MHSS and the MICS will minimize the impact of procedural or methodological changes on SMI trends.

The 2023 and 2024 MICS sample will be comprised of a probability subsample of adults aged 18 and older selected from NSDUH main study interview respondents. Unlike for the Clinical Validation Study (CVS) conducted as part of the 2020 NSDUH, there will be no alteration (i.e., increase) to the NSDUH sample to account for MICS minimal sample requirements. This is because everyone in the sample – those who participate in the MICS and those who do not – will receive the same version of the NSDUH main study survey. The only difference between the MICS and non-MICS groups of respondents is that those who participate in the MICS will receive a follow-up clinical interview after completing the main NSDUH survey.

The 2023 and 2024 MICS samples are designed to yield 2,000 interviews per year. Each year, the probability sample will be distributed across four calendar quarters, resulting in approximately 500 MICS follow-up clinical interviews per quarter.

The MICS interview will last approximately 60 minutes on average. Like the MHSS, respondents will receive a \$30 pre-incentive at the end of the NSDUH main interview. All clinical interviews will be conducted virtually via Zoom (phone and video). The MICS instrument will largely parallel the instrument that was used in the MHSS.

Clinical interviewers (CIs) will use the NetSCID (**Attachment MICS-1**), a computerized version of the Structured Clinical Interview for DSM-5(SCID) that calculates skip logic in real-time based on responses, leading to faster and more reliable administration than the non-computerized version. The NetSCID is hosted by TeleSage, Health Outcomes Inc.

2. **Purpose and Use of Information**

NSDUH Main Study:

The purpose of the NSDUH survey is to collect and report current data on substance use incidence and prevalence and mental health statistics for the civilian, non-institutionalized population aged 12 or older in the U.S., in each state, and the District of Columbia. The sample is sufficient to support SAEs in each state and the District of Columbia while maintaining efficiency for national estimates.

NSDUH data are used by SAMHSA, the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the Centers for Disease Control and Prevention (CDC), the Office of National Drug Control Policy (ONDCP), the U.S. Food and Drug Administration (FDA), other federal agencies, Congress, and various state and local government agencies interested in the incidence and prevalence of substance use and mental health statistics. The NSDUH questionnaire asks the minimum information necessary to meet the needs of federal policymakers and the substance use and mental health research, prevention, treatment and recovery communities. In conjunction with other data sources, NSDUH data are used to:

- design prevention programs;
- respond to inquiries on the extent of substance use;
- estimate treatment need;
- study the social and economic impact of substance abuse;
- identify the correlates of substance use;
- evaluate the overall impact that federal and state programs have on drug demand and reducing youth substance use;
- assess and improve outcomes of prevention and treatment services;
- measure program performance and improvement, including Quality Outcome Measures, Government Relations and Public Affairs (GRPA), and other requirements; and
- identify areas where serious substance abuse problems exist and provide assistance to states to help them develop and adopt targeted responses for those problems.

The Department of Health and Human Services (HHS) continues to affirm the need for annual NSDUHs as essential to the President’s annual Drug Control Strategy and federal objectives related to substance use. Because NSDUH is the nation’s primary source of reliable national substance use data on the U.S. population, this survey will ensure that SAMHSA and other federal, state, and local agencies have timely data available for release by late summer or early fall of the year following data collection. The ability to respond effectively and efficiently to the continually changing dynamics of the drug culture is critical to sound prevention and treatment strategies.

Because mental health issues are of critical importance to the nation and are key correlates of substance abuse, CBHSQ continues to include questions on mental health and utilization of mental health services in NSDUH. Questions on mental health, in conjunction with questions on substance use, treatment for substance use, and mental health services, greatly enhance the ability to characterize and understand the co-occurrence and treatment of mental illness and substance use problems in the United States. A detailed discussion of the questionnaire is presented in Section B.2.

Exploratory Pilot Testing in the U.S. Territories:

The purpose of exploratory pilot testing efforts is to explore expanding NSDUH data collection to the U.S. Territories. The phase approach will use respondent data for operational purposes only and exclude it from the main study dataset. The findings will provide SAMHSA with valuable insights for a successful full-scale data collection effort in future NSDUH surveys.

Mental Illness Calibration Study:

As mentioned above in A.1, the current NSDUH SMI estimates were developed under the 2008 – 2012 MHSS and reflect DSM-IV criteria. In the intervening years, the DSM was updated, and it is important to update the NSDUH mental illness estimates to reflect current criteria. The purpose of the MICS is to update NSDUH SMI estimates based on the DSM-5 criteria. Data on the prevalence of SMI are critical for NSDUH to monitor trends across the full spectrum of behavioral health including substance use and mental health.

During MICS data collection from January 2023 through December 2024, approximately 17,180 NSDUH adult main study interview respondents will be selected for the clinical interview at the end of the main study interview to produce a final sample size of at least 4,000 adult MICS follow-up clinical interviews (2,000 interviews per year).

3. Use of Information Technology

NSDUH Main Study:

In-Person Data Collection:

NSDUH data will be collected in a face-to-face interview setting in respondents’ homes using laptop computers. Field interviews will be administered using audio computer-assisted self-interviewing (ACASI) for sensitive questions, which represent most of the interview. The remainder of the interview will be administered by the field interviewer (FI) using computer-assisted personal interviewing (CAPI). This mode has been used on

NSDUH since 1999, while continually enhancing and expanding the interviewing program to take advantage of improvements in technology.

The CAPI/ACASI technology affords a number of advantages in the collection of NSDUH data. First, this methodology permits the instrument designer to incorporate into the questionnaire routings that might be overly complex or not possible using a paper-and-pencil instrument. The computer can be programmed to implement complex skip patterns and fill specific words based on the respondent's previous answers. FI and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, this methodology increases the consistency of the data. The computer can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving both time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. Third, in addition to time and money saved by minimizing edits needed to resolve discrepancies, the ACASI technology reduces social desirability bias.

CAPI/ACASI technology permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically in a FIPS-Moderate environment rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Tasks formerly completed by clerical staff are accomplished by the CAPI/ACASI program. In addition, the cost of printing paper questionnaires and associated mailing is eliminated. Finally, as noted above, the ACASI technology permits respondents, including nonreaders, to complete sensitive portions of the interview in total privacy. Providing the respondent with methodology that improves privacy and confidentiality makes reporting of potentially embarrassing, stigmatizing, or illegal behaviors (e.g., drug use, mental health issues) less threatening and enhances response validity and response rates.

Questions administered via ACASI in the NSDUH interview will continue to be read aloud to respondents using Text-to-Speech (TTS) software offered by Microsoft, Speech Platform, which features a dynamic implementation mode that uses the TTS engine to read question text in real time and eliminates the use of pre-recorded audio files altogether. Since the integration of the Speech Platform software into all NSDUH questionnaires since 2015, there have been no reported problems with the pronunciation of any words or phrases produced by the TTS voice in English or Spanish.

As part of in-person data collection, NSDUH will continue to use hand-held, Android-based tablet computers to conduct household screening interviews. The primary advantage of this computer-assisted methodology is accuracy in selecting the correct household member or members for an interview. The computer automatically selects the correct household member or members based on the demographic variables entered, thus substantially reducing the probability for human error. The hand-held computers also provide the benefits of complex case management tools, and quick secure electronic transfer of data. Additionally, it allows FIs to conduct screenings, interview respondent selection, and answer FI observation questions.

The laptops are FIPS-Moderate compliant and secured with 2-factor login, using Microsoft's integrated TPM-based 2-factor authentication mechanism for Windows 10 and BitLocker. The tablets are encrypted at rest using the FIPS 140-2 compliant device-level encryption facilities built into the implementation of the Android operating system running on each tablet.

Web-based Data Collection:

Those respondents who participate in the web-based NSDUH screening and/or interview may access those questionnaires from any device with internet access (computer, tablet, phone, etc.), using the website address provided to each respondent in the NSDUH Lead Letter (**Attachment A**). The website for the screenings and interviews features HTTPS encryption to provide sufficient security for all information entered from any device via any internet connection (public Wi-Fi, cellular, at-home Wi-Fi, etc.). However, while interview respondents will have the option to self-administer the questionnaire from any device with internet access, it will be recommended that they self-administer the interview from a laptop or desktop computer in their home to allow for the optimal viewing experience with the interview program via Blaise 5.

Mental Illness Calibration Study:

The selection of NSDUH main study interview respondents for the MICS follow-up clinical interview will be calculated at the end of NSDUH main study questionnaire. Individuals eligible for the MICS will be those aged 18 and older who chose to answer the NSDUH main study interview questions in English. Eligible respondents will be selected for the MICS based on their K6 nonspecific distress scale (Kessler et al., 2003), WHODAS score, and age group. Two hundred twenty-five strata will be constructed from combinations of 25 possible WHODAS and 9 possible K6 scores.

For those selected for the follow-up clinical interview, follow-up clinical interview recruitment scripts (included in **Attachment MICS-2**) are programmed within the NSDUH main study questionnaire and will be administered at the end of the main study interview using CAPI. The FI will not know if the respondent is selected for the follow-up clinical interview until the recruiting scripts appear on the laptop screen.

When selected for the follow-up clinical interview via the web-based main study interview, respondents will enter contact information if they agree to participate. This information will only be available on secure project systems for access by the CI assigned to contact the respondent for the follow-up clinical interview. If a respondent agrees to participate, the project's online scheduling system will be launched so the respondent can immediately schedule their follow-up clinical interview.

When selected for the follow-up clinical interview via the in-person main study interview, the FI and respondent will not know if the respondent is selected for the follow-up clinical interview until the recruitment scripts appear on the laptop screen. Contact information for those who agree to participate in the follow-up clinical interview will be entered into the laptop by the FI. This information will only be available on secure project systems for access by the CI assigned to contact the respondent for the follow-up clinical interview. The FI will also provide in-person respondents a scheduler card (**Attachment MIC-2**) that will provide instructions for accessing the project's

online scheduling system.

Before starting the follow-up clinical interview, CIs must complete the front-end section of the MICS Blaise Instrument (**Attachment MICS-3**), which includes the informed consent scripts. First, CIs read a script to confirm they are talking to the right person and that the respondent is in a safe and private location. Once confirmed, CIs continue reading the script to obtain informed consent from the adult respondent. The informed consent script (**Attachment MICS-4**) reminds respondents that information gathered during the interview will be kept completely confidential.

At the end of the informed consent script, an extended version of the informed consent (**Attachment MICS-5**) is offered to respondents who wish to know the full risks and benefits of the study, and how their information will be used. CIs offer to read the extended version aloud to respondents or provide a URL to so they can read it themselves.

After obtaining informed consent, CIs will then conduct the follow-up clinical interviews virtually via the Zoom platform. Respondents will join the meeting room to participate in a video call. For phone interviews, respondents will either call into the Zoom meeting or the CI will call the respondent directly from the Zoom meeting room. If the CI or respondent experiences technical difficulties with the Zoom platform that cannot be solved through troubleshooting, CIs will use the Interactive Intelligence (I3) system. The I3 system is a phone client setup on the CI laptops that allows them to call respondents directly from their personal phones without providing respondents with their phone number(s).

4. Efforts to Identify Duplication

NSDUH Main Study:

CBHSQ is in contact with major federal health survey managers and is aware of no other surveys that provide the level of detail on substance use and mental health issues as provided by NSDUH. NSDUH is the only survey of substance use and mental health in the United States with a sample size capable of producing high-quality national and separate state and substate incidence and prevalence estimates. NSDUH's large sample size also allows production of high-quality national estimates by detailed demographic characteristics. No duplication of effort has been identified.

Although other surveys and data systems collect information on substance use and substance use disorders, there are important methodological differences between these surveys and NSDUH that have implications on estimates of substance use prevalence. For example, Monitoring the Future (MTF) study is a NIDA-sponsored national survey that tracks substance use trends and related attitudes among adolescents in the U.S. It includes two components: a cross-sectional school-based survey of 8th, 10th, and 12th graders and an ongoing longitudinal panel study from each graduating class conducted by mail through 2017, with a transition to web-based data collection in 2018 and 2019. Because NSDUH is an annual survey of the civilian, noninstitutionalized population of the U.S. aged 12 or older, the two studies have different populations of interest. In addition, MTF does not survey dropouts, a group that NSDUH has shown to have higher rates of illicit drug use (Gfroerer, Wright, & Kopstein, 1997).

MTF conducts self-administered surveys in a school setting and by follow-up with a sample of 12th grade respondents after they complete high school. Research has shown that the mode of a survey has considerable effects on the results, especially with items that are prone to social desirability bias (Groves, 1989). NSDUH is conducted in the household or via the web using a computer-assisted instrument. Among the same student population covered by MTF, NSDUH substance use prevalence estimates are generally lower than MTF estimates, with differences tending to be more pronounced for 8th graders. The lower prevalence in NSDUH may be due to more underreporting in the household setting as compared to the MTF school setting, or more overreporting in the school setting as compared to the NSDUH household setting (Fowler & Stringfellow, 2001).

The Youth Risk Behavior Survey (YRBS) is another study that collects data on substance use within the U.S. YRBS is a component of CDC's Youth Risk Behavior Surveillance System (YRBSS), which biennially measures the prevalence of six priority health risk behavior categories: 1) behaviors that contribute to unintentional injury and violence; 2) tobacco use; 3) alcohol and other drug use; 4) sexual behaviors that contribute to unintended pregnancy and STD/HIV infection; 5) dietary behaviors; and 6) physical inactivity. The YRBS includes national, state, territorial, and local school-based surveys of high school students in grades 9 through 12. Hence, the YRBS does not provide annual estimates. Students completing the YRBS are given a self-administered questionnaire during a regular class period. Although the YRBS includes measures on tobacco, alcohol, and illicit drugs, it is not a comprehensive substance use survey. It includes only a few basic questions on these topics and a single question on feeling sad or hopeless in the past 12 months. It also includes questions on suicidality that differ from questions in NSDUH. Like MTF, this study is targeted at a different population and collects data in a different setting than NSDUH. As a result of these differences, the prevalence estimates of illicit drug use from YRBS are generally much higher than those from NSDUH.

Our assessment of the differences between NSDUH, MTF, and YRBS is supported by a series of papers published in the *Journal of Drug Issues* (Hennessy & Ginsberg, 2001) by an independent set of survey methods experts commissioned by HHS under contract to the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The experts suggest that differences in survey methodology among these studies may affect comparisons of prevalence estimates among youth. The assessment also found that all three surveys were well-designed and managed, but they each have different purposes. Given the methodological differences among these surveys, Harrison (2001) concluded that the similarities in what these surveys told policymakers and others about adolescent substance use in the United States were more worth emphasizing than the differences were. CHBSQ conducted a more recent comparison of adolescent substance use estimates from NSDUH, MTF, and the YRBS and reached similar conclusions (CBHSQ, 2012).

Another study that collects data on health-related behaviors is the Behavioral Risk Factor Surveillance System (BRFSS). BRFSS is an annual, state-based telephone survey of the civilian, noninstitutionalized adult population aged 18 or older and is sponsored by CDC. Since 2002, BRFSS has collected data from all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam using a computer-assisted telephone interviewing (CATI) design. BRFSS collects information on access to health care, health

status indicators, health risk behaviors (including cigarette and alcohol use), and the use of clinical preventive services. More than 400,000 adults are interviewed each year.

NHIS is an in-person household survey that has been conducted since 1957. Sample sizes are relatively large. For example, the 2021 NHIS had data for 30,673 households containing 37,743 individuals. Sample sizes for the Sample Adult Core and Sample Child Core were 29,482 and 8,261, respectively (National Center for Health Statistics, 2022).

Estimates of current cigarette smoking have tended to be higher in NSDUH than in BRFSS or the NHIS because the latter two surveys apply a somewhat different definition for current smoking (lifetime smoking of 100 or more cigarettes and reports of smoking cigarettes now versus any cigarette smoking in the past 30 days for NSDUH). NSDUH has shown higher rates of binge drinking than BRFSS. The use of self-administration in NSDUH, which is considered to improve privacy and confidentiality and yields higher reporting of sensitive behaviors, was offered as an explanation for the lower rates in BRFSS (Miller et al., 2004). In addition to these differences, it is important to note that BRFSS does not interview anyone under the age of 18 and NHIS estimates for cigarette smoking are for adults aged 18 or older. In contrast, NSDUH interviews respondents aged 12 or older.

The NHIS adult questionnaire includes three questions each on anxiety or depression among adults (frequency of feeling anxious/depressed, whether respondents were taking prescription medication, and the level of feelings of being anxious or depressed). In contrast, NSDUH includes a series of in-depth questions for adolescents aged 12 to 17 and adults aged 18 or older on lifetime and past year major depressive episode. NSDUH also has estimated the prevalence of any mental illness (defined as adults aged 18 or older who currently or at any time in the past year had a diagnosable mental, behavioral, or emotional disorder, regardless of the level of impairment in carrying out major life activities) and serious mental illness (defined as adults who currently or at any time in the past year had a diagnosable mental, behavioral, or emotional disorder resulting in substantial impairment in carrying out major life activities). NSDUH has used a combination of follow-up clinical interviews conducted by trained mental health clinicians with a subsample of adult NSDUH respondents from 2008 to 2012 and a statistical model predicting the likelihood of having mental illness was developed based on the clinical interviews.

The Household Pulse Survey collects information on household experiences during the coronavirus disease 2019 (COVID-19) pandemic, including mental health. As suggested by the National Center for Health Statistics (NCHS), the survey included modified versions of the two-item Patient Health Questionnaire (PHQ-2) to assess symptoms of depression and the two-item Generalized Anxiety Disorder (GAD-2) scale (National Center for Health Statistics, 2023). Given the quick turnaround, differing purposes, and the single data collection mode of the Household Pulse Survey, comparison of mental health estimates with those from NSDUH should be made with caution. NSDUH and the Household Pulse Survey used different measures (e.g., two questions in the Household Pulse Survey to estimate depression symptoms vs. a more extensive set of questions in NSDUH to estimate major depressive episode in the lifetime and past 12 months). The U.S. Census Bureau also notes the following on its website (<https://www.census.gov/data/experimental-data-products/household-pulse-survey.html>):

“The Census Bureau is fielding the Household Pulse Survey as a part of the agency’s Experimental Data Series; as such, data products may not meet some of the Census Bureau’s statistical quality standards. Data are subject to suppression based on overall response and disclosure avoidance thresholds.”

Some national mental health surveys were conducted several years ago. For example, the National Epidemiologic Survey on Alcohol and Alcohol Related Conditions (NESARC), which was sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), was another study that contained assessments of drug use, abuse, and dependence, as well as associated mental disorders. While NSDUH is an annual survey of the civilian, noninstitutionalized population of the U.S. aged 12 or older, NESARC was designed to make inferences for persons aged 18 or older and is conducted in waves (2001/2002, 2004/2005 and 2012/2013). Although NESARC was designed to be a longitudinal survey, the design for most recent administration in 2012 to 2013 was cross-sectional. Another methodological difference between the two surveys is that sensitive questions in NSDUH are self-administered via ACASI whereas NESARC is all interviewer-administered. There is evidence to suggest that methodological features, including factors related to privacy and anonymity, and differences in diagnostic instrumentation result in different prevalence estimates; in particular, NSDUH has shown higher rates of use of illicit drugs than NESARC (Gruza et al., 2007).

The National Comorbidity Study (NCS) and National Comorbidity Study Replication (NCS-R) were conducted with adults in 1990 to 1992 for the NCS and in 2001 to 2003 for the NCS-R. The National Comorbidity Survey Replication Adolescent Supplement (NCS-A) for adolescents aged 13 to 17 was conducted from 2001 to 2004.

Mental Illness Calibration Study:

CBHSQ is in contact with all major federal health survey managers and is aware of no other efforts to recalibrate the estimates of SMI using the DSM-5 criteria. To date, no duplication of effort has been identified.

5. Involvement of Small Entities

The NSDUH main study and MICS does not involve small businesses or other such entities.

6. Consequences If Information Is Collected Less Frequently

NSDUH Main Study:

The existence of substance use patterns and behaviors is a rapidly evolving and changing phenomenon that calls for timely measurement and analysis of the data. It is imperative to continue the survey on an annual basis for three reasons:

- 1) the statutory mandate for annual data collection on the national incidence and prevalence of substance use;
- 2) the continued demand within SAMHSA, ONDCP, and other federal agencies for data on the nature and size of the nation’s substance use problem; and

- 3) the requirement for current data for each of the 50 states, and the District of Columbia to evaluate the effectiveness of programs designed to reduce the use of illicit substances.

Mental Illness Calibration Study:

The MICS data collection is designed to update NSDUH SMI estimates based on the DSM-5 criteria. Data on the prevalence of SMI are critical for NSDUH to monitor trends across the full spectrum of behavioral health including substance use and mental health. To meet this deadline, the MICS must conclude by December 2024 so results can be analyzed, and the NSDUH SMI indicator is updated to reflect the DSM-5. The MICS is a one-time collection and will not be repeated.

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

This information collection for both NSDUH main study and the MICS fully complies with 5 CFR 1320.5(d)(2).

CBHSQ requests an exemption to the revisions of race and ethnicity data classification related to revised Statistical Policy Directive No 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), effective March 28, 2024.

In the “Revisions to OMB's Statistical Policy Directive No. 15” Federal Register Notice (FRN) published on March 29, 2024 (89 FR 22182), OMB acknowledges that “*certain programs that involve interconnected data across multiple agencies or offices, or that rely on data collected and provided by non-Federal entities, may take longer to implement than programs like statistical surveys.*”

There is a need to align the NSDUH implementation schedule for SPD 15 with the Census Bureau’s implementation schedule because Census Bureau data are used in the NSDUH weighting procedures. Until updated race/ethnicity data from the Census Bureau are released, NSDUH will need to post-stratify the data back to the race and ethnicity categories prior to the revisions of SPD 15. This means that Middle Eastern or North African (MENA) category would have to be collapsed with White in the NSDUH weighting models. It does not appear possible to bridge NSDUH data between “White” under the previous SPD 15 and the new standards that include MENA because NSDUH data does not allow determination of whether some respondents who reported “White” would have chosen MENA if given the opportunity. For these reasons, CBHSQ requests delaying updates to the race/ethnicity questions for 2025.

8. Consultation Outside the Agency

NSDUH Main Study:

A Federal Register notice was published on March 4, 2024 (89 FR 15601). Two public comments were received on the NSDUH. The public comments and SAMHSA’s responses can be found in the Public Comments Response Matrix (**Attachment Y**).

One reviewer requested access to the Spanish version of the questionnaire specifications (see public comment 1). SAMHSA appreciates the request, however, the Spanish translation used during the Puerto Rico pilot is not available to the public. The other reviewer suggested modifications to the nicotine module by adding questions about

heated tobacco products, nicotine pouches, brands of e-cigarettes that participants use, and nicotine dependence and e-cigarettes (see public comment 2). Due to insufficient space in the interview and/or input from subject matter experts, these suggested modifications will not be implemented in the NSDUH.

Appendix A of Supporting Statement B contains a listing of current consultants on the NSDUH main study.

There are no unresolved issues resulting from these consultations.

Mental Illness Calibration Study

The same Federal Register notice published on March 4, 2024 (89 FR 1560) for the NSDUH main study also included the MICS. No public comments were received on the MICS.

There are no current consultants on the MICS.

9. Payment to Respondents

NSDUH Main Study

Adult respondents (aged 18 or older) and youth respondents (aged 12 to 17) are given \$30.00 upon completion of the NSDUH main study interview. Those who complete the interview in person receive cash from an FI. Those who complete the interview via the web can choose to receive an electronic or physical gift card of \$30. On October 18, 2001, the use of a \$30.00 incentive was approved by OMB for use in the 2002 NSDUH. The 2002 NSDUH experienced an increase in the weighted overall response rate (screening * interviewing) from 67 percent to 71 percent. Prior OMB approval was provided for the continued use of the \$30.00 incentive for the 2003-2024 NSDUHs. The weighted overall response rates for 2001-2022 appear in Table 1. This submission calls for the same incentive plan, whereby a \$30.00 incentive will be given to respondents upon completion of the NSDUH interview. The incentive is mentioned in the following respondent materials: Lead Letter (**Attachment A**); In-Person Question & Answer (Q&A) Brochure (**Attachment B**); Web-Based Q&A Brochure (**Attachment WEB-1**); Tablet Screening Video Scripts (**Attachment C**); Contact Cards (**Attachment D**); In-Person Study Description (**Attachment E**); Web-Based Study Description (Attachment WEB-2); Unable-to-Contact and Controlled Access Letters (**Attachment F**); Web Follow-up Letters (**Attachment Web-3**); Refusal Letters (**Attachment G**); and Interview Incentive Receipt (**Attachment H**).

Since implementation in 2002, the \$30.00 incentive used in NSDUH has contributed to the annual overall survey response rates. However, NSDUH screening, interview, and overall response rates have generally declined since 2006 (Table 2).

Table 1. Overall NSDUH Weighted Response Rates, by Year

Year	Overall Weighted Response Rate
2001	67%
2002	71%
2003	70%

2004	70%
2005	70%
2006	67%
2007	66%
2008	66%
2009	67%
2010	66%
2011	65%
2012	63%
2013	60%
2014	58%
2015	55%
2016	54%
2017	51%
2018	49%
2019	46%
2020	16%
2021	10%
2022	12%

Table 2. Screening, Interview, and Overall NSDUH Weighted Response Rates, by Year

Year	Screening	Interview	Overall
2006	90.23%	74.21%	66.96%
2007	89.07%	73.87%	65.80%
2008	88.62%	74.24%	65.79%
2009	88.40%	75.56%	66.79%
2010	88.42%	74.57%	65.94%
2011	86.98%	74.38%	64.69%
2012	86.07%	73.04%	62.87%
2013	83.93%	71.69%	60.18%
2014	81.94%	71.20%	58.34%
2015	79.69%	69.25%	55.19%
2016	77.88%	68.94%	53.69%
2017	75.08%	67.45%	50.64%
2018	73.30%	66.78%	48.95%
2019	70.50%	64.92%	45.77%
2020	25.71%	60.41%	15.53%
2021	22.21%	46.24%	10.27%
2022	25.46%	47.43%	12.08%

2020 In-Person and Web-Based Response Rates:

Data collection methods were modified during 2020 due to the COVID-19 pandemic to ensure the safety of the public and FIs. Quarter 1 (January to March 2020) was completed using standard NSDUH protocols with in-person data collection. However, Quarter 1 data collection ended 15 days early when work was suspended on March 16, 2020.

Data collection resumed in Quarter 4, but in-person data collection was limited to a small number of eligible states and counties due to COVID-19 infection rates. Web-based

screening and interviewing procedures were developed to account for suspended data collection in Quarter 2 and most of Quarter 3 and to maximize the number of completed interviews for national estimates. NSDUH data collection in Quarter 4 used in-person and web-based procedures.

However, because a vast majority of the interviews completed in Quarter 4 were completed via the web-based option (93%), comparisons of response rates between Quarter 1 and Quarter 4 can be thought of as differences between in-person (Quarter 1) and web-based (Quarter 4) response rates.

Although the addition of web-based data collection in Quarter 4 increased the number of interviews that were completed, web-based data collection yielded lower response rates than in-person data collection.

Web-based data collection remained an option for individuals who preferred to complete the interview on the web.

2021 In-Person and Web-Based Response Rates:

Like Quarter 4 of 2020, data collection in 2021 used both in-person and web-based procedures. In-person data collection was limited to eligible areas based on COVID-19 infection rates. Although the addition of web-based data collection provided a means for collecting data in areas where in-person data collection was not feasible, web response rates were lower than in-person response rates as expected. Therefore, a larger sample of dwelling units (DUs) was required.

2022 In-Person and Web-Based Response Rates:

The use of in-person and web-based data collection procedures continued in 2022. However, at the beginning of Quarter 1, in-person data collection was still limited to eligible areas based on COVID-19 infection rates. Starting February 3, 2022, all areas were eligible for in-person data collection. Although FIs were able to collect data in most areas, in-person response rates were much lower than they were before the COVID-19 pandemic. Further, web response rates were lower than in-person response rates, as expected. For these reasons, a large sample of DUs was required in 2022.

Mental Illness Calibration Study:

The MICS follow-up clinical interview will constitute an additional burden on respondents and may make it more difficult to obtain respondent participation. To maintain adequate response rates, SAMHSA believes it is necessary to offer MICS respondents an additional \$30 incentive for agreeing to complete the follow-up clinical interview, which takes about the same amount of time as the NSDUH main study interview, so an equitable incentive is prudent. Evidence indicates that prepaid incentives, like the MICS incentive, are usually more effective than promised (or conditional) incentives (Gelman, Stevens, & Chan, 2002; Singer, 2002; Singer & Ye, 2013).

Respondents who agree to complete the follow-up clinical interview will receive a total of \$60 at the end of the NSDUH main study interview – consistent with incentive amounts provided to respondents as part of the 2008-2012 NSDUH MHSS. The additional incentive for the MICS follow-up clinical interview is mentioned in the following respondent materials: Follow-up Clinical Interview Recruitment Scripts

(included in **Attachment MICS-2**), Follow-up Study Description (**Attachment MICS-6**), and the Follow-up Interview Incentive Receipt (**Attachment MICS-7**).

Web respondents who agree to complete the follow-up clinical interview at the end of the NSDUH main study interview will be asked to select a preferred method for receiving the additional \$30 – either an electronic or physical gift card.

In-person respondents who agree to participate in the follow-up clinical interview will receive \$30 cash from the FI.

10. Assurance of Confidentiality

NSDUH Main Study:

Data will be kept private to the extent allowed by law. Concern for the confidentiality and protection of respondents' rights has always played a central part in the implementation of NSDUH and will continue to be given the utmost emphasis.

FIs are thoroughly educated in methods for maximizing a respondent's understanding of the government's commitment to confidentiality. Furthermore, FIs make every attempt to secure an interview setting in the respondent's home that is as private as possible, particularly when the respondent is a youth. The Contractor's Institutional Review Board (IRB) was granted a Federalwide Assurance (**Attachment I**) by the Office for Human Research Protections (OHRP) and HHS in compliance with the requirements for the protection of human subjects (45 CFR 46). The Contractor's IRB will approve the protocols and consent forms for the NSDUH prior to any respondent contact. The IRB's primary concern is protecting respondents' rights, one of which is maintaining the confidentiality of respondent information. By obtaining IRB approval for NSDUH procedures and materials, CBHSQ is assured that respondent confidentiality will be maintained.

On the data files, respondents are distinguished only by a unique number assigned to screenings and interviews. Although the unique number is associated with a location number and a dwelling unit number, the Contractor deletes this location information before the delivery of data to CBHSQ. The dwelling unit address information, which is maintained in a separate file for Contractor use in sampling, fielding, and weighting cases, is purged at the completion of data processing.

After delivery and acceptance of the final survey data files, all records of sample dwelling unit (SDU) addresses are destroyed. The permanent sampling records show only the general location in which interviews were conducted; there is no record of specific dwelling units contacted.

This data collection is subject to the Privacy Act of 1974.¹ Furthermore, Privacy Impact Assessment (PIA) documentation for NSDUH is reviewed each year as part of NSDUH's annual system security assessments. Subsequently, the PIA documentation in the HHS system is updated by SAMHSA personnel as needed. The most recent review cycle was in November 2020.

In-Person Data Collection:

¹ The SAMHSA System of Record Notice covering NSDUH is 09-30-0036 and 09-30-0049. See <http://samhsa.gov/privacy/pia> for more information.

Several procedures ensure that respondents' rights are protected during in-person data collection. First, the FI introduces themselves and the study by reading the Introduction and Informed Consent Scripts (**Attachment J**) aloud to each interview respondent and if needed, to a parent/guardian of a youth respondent. This statement will appear in the Showcard Booklet (**Attachment K**). As part of the process for obtaining informed consent, respondents are given an In-Person Study Description (**Attachment E**), which includes information on the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, included as Title V in the E-Government Act of 2002, P.L. 107-347) and the protection that it affords. This statute prohibits disclosure or release, for non-statistical purposes, of information collected under a pledge of confidentiality.

Specifically, the Study Description states that respondents' answers will be used only by authorized personnel for statistical purposes and cannot be used for any other purpose. If a respondent is aged 12 to 17, when the youth is selected for the NSDUH interview, the FI can read the Parental Introductory Script (**Attachment L**) to the parent or guardian requesting permission to speak with the youth about NSDUH. After that introduction, parental consent for the interview is obtained from the selected respondent's parent or guardian, youth assent is requested and at least one parent, guardian or another adult must remain present in the home throughout the interview.

Under CIPSEA, data may not be released to unauthorized persons. CIPSEA safeguards the confidentiality of individually-identifiable information acquired under a pledge of confidentiality by controlling access to, and uses made of, such information. CIPSEA includes fines and penalties for any knowing and willful disclosure of individually-identifiable information by an officer, employee, or agent of SAMHSA. Willful and knowing disclosure of protected data to unauthorized persons is a felony punishable by up to five years imprisonment and up to a \$250,000 fine.

As CIPSEA agents, all Contractor staff complete an annual CIPSEA training and sign a notarized Confidentiality Agreement (included in **Attachment M**). FIs also complete CIPSEA and project training on ensuring respondent confidentiality and will have signed a notarized Data Collection Agreement (included in **Attachment M**) certifying they will keep all respondent information confidential.

After obtaining informed consent, FIs make every attempt to secure an interview setting that is as private as possible. In addition, the interview process, by design, includes techniques to afford privacy for the respondent. The ACASI portion of the questionnaire maximizes privacy and confidentiality by giving control of the sensitive questionnaire sections directly to the respondent. The ACASI methodology allows the respondent to listen to questions through headphones and/or to read the questions on the computer screen, and then key his or her own responses into the computer via the keyboard. At the end of the ACASI portion, the respondent's answers are locked so no one, including the FI, can see the responses until after the data are transmitted, processed, and aggregated by the Contractor in a FIPS-Moderate environment.

Each day they work, FIs electronically transmit all completed screening and interview data to the Contractor's servers via secure encrypted data transmission in a FIPS-Moderate environment. As part of that FIPS-Moderate compliance, the laptops and

tablets are also protected with FIPS 140-2 compliant device-level encryption and the laptops require two-factor authentication to access.

Web-based Data Collection:

Those choosing to complete the interview via the web-based option will be able to access their interview at a later time of their choosing (until the end of the quarterly data collection period) by using the website address provided on the Lead Letter – the same address for the screening – and inserting the participant code unique to that SDU. As currently designed, the participant code in the Lead Letter is a globally-unique system identifier that is assigned to households when the web sample is generated and acts as a primary key in the underlying databases.

Once the interview respondent uses the participant code to access their assigned interview, each will first have to review the informed consent text. This text provides many of the same elements as the informed consent text read to in-person respondents by FIs but has been updated to incorporate text specific to the web mode administration.

This text, included in the Web-based CAI Questionnaire (**Attachment Web-4**) asks each adult interview respondent to confirm they are 18 years old or older and that they are at home in a private location where no one else can see their answers. Also, the screen with this informed consent text will contain a link to the NSDUH Web-Based Study Description (**Attachment WEB-2**); when clicked, a separate window will display the Study Description for the respondent to review, download as a PDF and/or print at their discretion.

As an additional layer of security, after advancing past the informed consent text, each adult respondent will be required to set a unique 4-digit PIN code of their own choosing before they begin self-administering interview questions. This will prevent anyone else within the dwelling unit from accessing the interview and seeing answers to questions.

Before a web-based interview with a youth respondent can begin, a parent/guardian of that youth respondent (and the youth selected as the interview respondent) must speak with a telephone interviewer. Parents will be given a telephone number displayed at the end of the web screening (and in follow-up letters mailed after the screening) to place a call into the Contractor's call center to speak with the telephone interviewer.

At that time, the telephone interviewer will read an informed consent script to the parent over the telephone. The script read by the telephone interviewer to the parent includes the expectation the parent and youth be at home, youth must be in a private location, parents cannot view answers, nature of the questions, etc. After speaking with the parent, the telephone interviewer will then read an assent script to the youth respondent about the content of the interview. A copy of this script is included as **Attachment WEB-5**.

A text version of this youth assent script will also be displayed again within the online interview for the youth respondent to read and acknowledge before they begin the interview. Finally, similar to the adult interviews, as an additional layer of security, each youth respondent will be required to set a unique 4-digit PIN code of their own choosing before they begin self-administering interview questions. This will prevent anyone else within the dwelling unit from accessing the interview and seeing answers to questions.

Mental Illness Calibration Study:

The MICS will incorporate several procedures to ensure respondents' rights will be protected. The FI will introduce the follow-up clinical interview with recruitment scripts (**Attachment MICS-2**). These scripts will appear on the computer screen at the end of the main study interview and will be read aloud by the FI to each interview respondent selected for the MICS. As part of the process for obtaining informed consent for the follow-up clinical interview, respondents will be given a Follow-up Study Description (**Attachment MICS-6**) by the FI, which includes information on CIPSEA and the protection it affords. Specifically, the Follow-up Study Description states that respondents' answers will only be used by authorized personnel for statistical purposes and cannot be used for any other purpose. The dwelling unit address information, which is maintained in a separate file for Contractor use in sampling, fielding, and weighting cases, as well as the respondent's first name, phone number, and email address, will be destroyed when all final data files are delivered to SAMHSA.

The respondent's first name, phone number, and email address will be collected within the main study interview and will be used only for recontact purposes. Contact information for respondents will be stored in a dedicated secure database in the FIPS-Moderate network zone, and not recombined with interview responses or clinical interview result data. Upon completion of data collection for a quarter, the collected data will be converted into a SAS data file format. Identifiers used for recontacting respondents will be stripped and dropped from the SAS data files and merged onto the master data file. All personally identifiable information (PII) will be removed from the data files prior to removal from the FIPS-Moderate environment, and prior to delivery to SAMHSA.

CIs will be assigned cases automatically based on the availability they entered into the calendar system on the project's private site, which will reside within the FIPS-Moderate network zone where access requires two-factor authentication. Cases will be accessed by CIs via the project's private site on a project-issued laptop computer. CIs will be required to confirm that project-issued computers will not contain any electronic notes from interviews and will not have other programs or websites running in the background while they are accessing the site.

The follow-up clinical interview will be conducted via Zoom or by telephone by clinicians trained in the administration of the NetSCID (**Attachment MICS-1**). Each clinical interview case will be identified by a case-specific ID code unique to that case that identifies the main study interview from which the follow-up clinical interview was generated. No PII including respondent name, telephone number, email address, or other contact information will be recorded in the MICS instrument.

To initiate interviews, CIs will open the interview-specific Zoom meeting then either: (1) wait for the respondent to join the call (video or phone) or (2) directly call the respondent. The Zoom system will also be utilized for all interview recordings, upon respondent permission. All recordings will be saved on a secure private project website in the FIPS-Moderate network zone.

Access permissions to files and data sets on the network are carefully controlled using a combination of domain usernames/passwords and other forms of authentication, such as SQL Server logins. Usernames and passwords on the networks are subject to enforced

security checks, password length requirements, and corporate policies requiring adherence to security procedures. As a project operating policy, all sensitive and PII data are stored only on file servers running and implementing full Microsoft or UNIX security, within the Contractor's FIPS-Moderate network zone.

Following the conclusion of the MICS data collection, analyses of data will be conducted. The Restricted Use Data File (RUF) will be stored securely on file storage appliances within the FIPS-Moderate network zone and can be accessed by only a small group of authorized project staff. Any use of RUF files is contained entirely within the FIPS-Moderate network zone.

The permanent sampling records will contain no record of which addresses were selected for the MICS.

11. Questions of a Sensitive Nature

NSDUH Main Study:

Many of the NSDUH main study interview questions concern topics likely to be of a sensitive nature to many respondents. Many safeguards, including the ACASI mode of questionnaire administration for in-person interviews, improve the privacy of data collected on sensitive issues. As part of the interview introduction, respondents are informed why the information is necessary, who sponsors the study, provided consent text to conduct an interview, and informed of the procedures that ensure confidentiality. As noted in section A.10, for respondents between the ages of 12 and 17 verbal consent is obtained from both the parent or guardian and then the youth. (See **Attachment J**, Introduction and Informed Consent Scripts, for verbal consent text.) Once parental consent is obtained, every attempt is made to ensure the actual interview is conducted without parental observation or intervention, though at least one parent, guardian or another adult must remain present elsewhere in the home throughout the interview.

Answers to sensitive questions, including all substance use, mental health, and sexual orientation and attraction questions, are obtained by closed interview design. In the ACASI portion of the in-person interview, the respondent enters his or her answers directly into the computer. The FI does not see these answers.

As explained in section A.10, all NSDUH data collected in person by FIs are transmitted regularly to the Contractor via secure encrypted data transmission in a FIPS-Moderate environment and distinguished only with a unique number, which is a code associated with the SDU. The questionnaire data are processed immediately upon receipt at the Contractor's facilities, and all associations between a questionnaire and the respondent's address are destroyed after all data processing activities are completed. The listings of SDU addresses are kept under secured conditions and destroyed after all data processing activities are completed.

All data collected as part of web-based screenings and interviews are protected by the same FIPS-Moderate security controls employed as part of in-person data collection while all data are at rest and in transit. The screening and interviewing website will utilize TLS encryption within HTTPS to protect screening and interview data while in transit across the internet. For those respondents who participate in a web-based screening and/or interview, they will self-administer those instruments via a secure web site, where

they will be asked to authenticate themselves using the unique alpha-numeric participant code provided to them in the Lead Letter they receive.

Mental Illness Calibration Study:

Some of the sensitive questions contained in the MICS follow-up clinical interview may cause some respondents to feel emotional distress. All CIs will be trained mental health professionals who can recognize signs of cognitive impairment or significant distress in respondents. A Distressed Respondent Protocol (**Attachment MICS-8**) will be used to guide CIs on helping respondents who disclose intent to harm themselves or others. CIs will remain alert for signs of distress and utilize their professional mental health training to identify when a respondent exhibits active suicidal or homicidal symptoms or seems upset during a follow-up clinical interview. In these circumstances, the CI will stop the interview and follow the appropriate guidelines outlined in the Distressed Respondent Protocol. The protocol will also include provisions for respondents who may not be in imminent danger of harm, but who become distressed or agitated during the follow-up clinical interview. CIs will not report any information about the respondent to anyone except in accordance with this protocol. The Distressed Respondent Protocol also includes procedures to be followed if a respondent reveals information that leads the CI to believe that someone is being abused or neglected. The Distressed Respondent Protocol for the MICS was developed based on similar versions used on the Mental Disorder Prevalence Study (MDPS) from 2020–2022.

The MICS interview procedures are designed to reduce and mitigate the risk associated with revealing potentially sensitive information. First, CIs will administer the follow-up clinical interview over Zoom, either video or phone, from a private location in their home or office. During the informed consent process, CIs will ensure the respondent is in a private location. Secondly, like main study FIs, all MICS CIs will complete SAMHSA- and RTI-required trainings on confidentiality and privacy, which state they agree to treat as confidential all information secured during interviews or obtained in any project-related way.

12. Estimates of Annualized Hour Burden

NSDUH Main Study

The NSDUH sample has been designed to yield approximately 67,507 completed interviews combined across both modes of administration. It will be necessary to sample approximately 917,031 households and complete approximately 285,894 screenings to obtain the requisite number of interviews. This sample size is required to ensure reliable state-level estimates for each of the 50 states, and the District of Columbia, as well as estimates by various sub-groupings such as race, ethnicity, and age.

Based on experience with the 2023 screening process, administration of the screening questions is expected to take an average of five minutes per SDU regardless of mode. Initial timing data indicate the NSDUH questionnaire used in 2023 took about 60 minutes to administer, on average. Since there are only a few changes to the questionnaire for 2025, it is estimated that the average amount of time required to administer (or self-administer for the web mode) the In-Person CAI Questionnaire (**Attachment N**) will remain the same, 1.008 hours.

Screening and interview verification of in-person contacts each take an average of four minutes and are administered only to a subsample of the cases. An approximate 15 percent random sample of each FI's completed interviews will be verified. In addition, the following completed in-person screening codes that do not result in a respondent being selected for an in-person interview will be verified:

- vacant;
- not a primary residence;
- not a dwelling unit;
- contain only military personnel;
- include only residents who will live in the household for less than half of the quarter; and
- no one was selected for interview.

The data collection field period for each NSDUH survey year is 12 months, spanning from January through December. The annualized estimated respondent burden for the 2025 NSDUH is shown in Table 3.1. The hourly wage of \$20.66 was calculated based on weighted data from the 2022 NSDUH and respondents' reported personal annual income.

Table 3.1 Annualized Estimated Respondent Burden for 2025 NSDUH

Instrument	No. of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Hourly wage rate	Total hour cost
Household Screening	285,894	1	285,894	40.083	23,729	\$20.66	\$490,241
Interview	67,507	1	67,507	71.008	68,047	\$20.66	\$1,405,851
Screening Verification	6,004	1	6,004	40.067	402	\$20.66	\$8,305
Interview Verification	7,088	1	7,088	40.067	475	\$20.66	\$9,814
Total	366,493		366,493		92,653		\$1,914,211

Mental Illness Calibration Study

Zero respondent burden hours are anticipated for MICS in 2025. The MICS is scheduled to end on December 31, 2024.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital, startup, operational, or maintenance costs to respondents for the NSDUH main study or the MICS.

14. Estimates of Annualized Cost to the Government

Total costs associated with the NSDUH are estimated to be \$62,051,048 over a 48-month contract performance period. Of the total costs, \$53,186,162 are for contract costs (e.g., sampling, data collection, processing, reports) and approximately \$8,864,886 represents

CBHSQ costs to manage/administrate the survey. The annualized cost is approximately \$15,512,762.

15. Changes in Burden

Currently, there are 82,331 total burden hours in the OMB inventory. SAMHSA is requesting 92,653 burden hours for each survey year starting with 2025. This increase of 10,322 burden hours is due to a decline in main study response rates, which results in the need to contact additional dwelling units to yield the targeted number of completed interviews.

16. Time Schedule, Publication and Analysis Plans

Plans for the 2025 survey data involve six major types of data products: 1) National Reports (available at the annual HHS press release of NSDUH data or soon thereafter); 2) state findings; 3) substate findings; 4) Public Use Data File (PUF); 5) Restricted Use Data File (R-DAS); and 6) Research Data Centers. Descriptions of major products, as well as approximate delivery dates follow. Table 4 includes a schedule for the 2025 NSDUH.

1) NSDUH National Report (September 2026). SAMHSA will release a national report that covers topics related to substance use and mental health issues among the civilian, noninstitutionalized population aged 12 or older, such as estimates in substance use and mental health issues, suicidal thoughts and behavior among adults aged 18 or older, receipt of substance use treatment and mental health services, and initiation of substance use. The 2022 National Report was released in November 2023.

2) State Findings (December 2026/February 2027). Data from the combined 2021 and 2022 NSDUHs will be used to provide state estimates (for the 50 states and the District of Columbia) for up to 36 substance use and mental health outcomes. These estimates will be produced using small area estimation methodology. Along with the 2024-2025 state small area estimates, significant tests of change between the 2023-2024 and the 2024-2025 state population percentages will be included.

3) Substate Findings (April 2027/June 2027). Data from the combined 2023, 2024, and 2025 NSDUHs will be used to provide estimates for substate regions (about 400) within all states for up to 36 substance use and mental health outcomes. These estimates will be produced using small area estimation methodology. Along with the 2023-2025 substate small area estimates, significant tests of change between the 2021-2023 and the 2023-2025 substate region population percentages will be included.

4) Public-Use Data File (PUF) (October 2026). The restricted-use Analytic Data File serves as the starting point for the PUF. Each analytic variable is reviewed for potential disclosure risk. Based on this review, each variable is retained, deleted, or treated further (e.g., collapsed categories) for the PUF. Recoded and statistically imputed variables created for the First Findings reports and Detailed Tables that are produced each year also are included on the PUF, as long as these variables do not pose a disclosure risk. The data treatment process has been enhanced over several years to ensure the data remain confidential.

5) Data File for the Restricted-Use Data Analysis System (R-DAS) (Ongoing). The R-DAS is a combination of various Analytic Data File variables that are continuous across study years. There are currently twelve pair-year data files, 2002-2003, 2004-2005, 2006-

2007, 2008-2009, 2010-2011, 2012-2013, 2014-2015, 2015-2016, 2016-2017, 2017-2018, 2018-2019, and 2021-2022. Similarly, there are five 4-year files, 2002-2005, 2006-2009, 2010-2013, 2014-2017 and 2015-2018, two eight-year files, 2002-2009 and 2006-2013, two 10-year files, 2002-2011 and 2010-2019, one 12-year file, 2002-2013, one fourteen year, 2002-2015, one fifteen year, 2002-2016 and one sixteen year, 2002-2017. The future development of additional combined files is currently under internal consideration. Although there is no treatment to the variables on the files delivered to the Substance Abuse and Mental Health Data Archive (SAMHDA) and SAMHSA, R-DAS files are available only for online analysis (i.e., R-DAS files cannot be downloaded). A set of variables also are excluded from any R-DAS data file due to disclosure issues. Further, any variables that can determine a specific study year are also excluded.

6) Restricted-use Data Centers (RDC) (Ongoing). SAMHSA has partnered with the National Center for Health Statistics (NCHS) to host NSDUH restricted-use data at their Research Data Centers (RDCs). RDCs are secure facilities that provide access to a range of restricted-use microdata for statistical purposes.

Table 4. Project Schedule for the 2025 NSDUH

Activity	Time Frame
Design and select area frame sample	January 2024 to March 2024
Prepare field Segment Kits	February 2024 to May 2024
Prepare for and conduct field staff training	February 2024 to January 2025
Recruit/train field staff to list SDUs	May 2024 to July 2024
Conduct field listing and subsequent keying of SDUs	August 2024 to January 2025
Program the screening and interview instruments	August 2024 to October 2024
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2024 to January 2025
Conduct screenings and interviews	January 2025 to December 2025
Conduct full-year data processing and file preparation	January 2026 to March 2027
Prepare Trend Tables and Special Tabulations: - Finalize Shells - Finalize Annual Tables	March 2026 June 2026
Prepare Raw Data Files	May 2026
Release Preliminary Weighted Data Files	May 2026
Finalize Sampling Error Report	July 2026
Prepare State Findings	August 2026 to March 2027
Release Final Analytic Data File and documentation	September 2026
Publish First Findings Reports	September 2026
Release Public Use Data File	October 2026
Publish Methodological Resource Book	April 2027

17. Display of Expiration Date

The OMB expiration date will be displayed.

18. Exceptions to Certification Statement

The certifications are included in this submission and fully comply with 5 CFR 1320.9.

Attachments

Attachment A.	Lead Letter
Attachment B.	In-Person Question & Answer Brochure
Attachment C.	Tablet Screening Video Scripts
Attachment D.	Contact Cards – Sorry I Missed You Card and Appointment Cards
Attachment E.	In-Person Study Description
Attachment F.	Unable-to-Contact and Controlled Access Letters
Attachment G.	Refusal Letters
Attachment H.	Interview Incentive Receipt
Attachment I.	Federalwide Assurance
Attachment J.	Introduction and Informed Consent Scripts
Attachment K.	Showcard Booklet
Attachment L.	Parental Introductory Script
Attachment M.	Confidentiality Agreement and Data Collection Agreement
Attachment N.	In-Person CAI Questionnaire
Attachment O.	NSDUH Highlights
Attachment P.	Participant Code Card
Attachment Q.	Engaging Respondents Handout
Attachment R.	Data Security Handout
Attachment S.	State Highlight
Attachment T.	In-Person Screening Questions
Attachment U.	Certificate of Participation
Attachment V.	CATI Verification Scripts
Attachment W.	Doorperson Card
Attachment X.	Nonresponse among Sample Members Aged 50 and Older Report
Attachment Y.	Public Comments Response Matrix
Attachment WEB-1.	Web-based Question & Answer Brochure
Attachment WEB-2.	Web-based Study Description
Attachment WEB-3.	Web-based Follow-up Letters
Attachment WEB-4.	Web-based CAI Questionnaire
Attachment WEB-5.	Parental Permission Script
Attachment WEB-6.	Web-based Screening Questions

Attachment WEB-7.	Incentive Thank You Letters
Attachment MICS-1.	NetSCID Instrument Specs
Attachment MICS-2.	Follow-up Interview Recruitment Scripts
Attachment MICS-3.	Follow-up Interview Field Scheduler Card
Attachment MICS-4.	MICS Blaise Instrument
Attachment MICS-5.	Follow-up Interview Informed Consent
Attachment MICS-6.	Follow-up Interview Extended Informed Consent
Attachment MICS-7.	Follow-up Study Description
Attachment MICS-8.	Follow-up Interview Incentive Receipt
Attachment MICS-9.	Follow-up Interview Distressed Respondent Protocol
Attachment MICS-10.	Scheduler Automated Emails
Attachment MICS-11.	Follow-up Interview Text System Messages
Attachment MICS-12.	Email and Voicemail Contacting Scripts
Attachment MICS-13.	Follow-up Interview Confirmation Scripts
Attachment MICS-14.	Follow-up Interview Refusal Letter Template
Attachment MICS-15.	Follow-up Interview Unable to Contact Letter Template
Attachment MICS-16.	Follow-up Interview Scheduling Letter Template
Attachment MICS-17.	CATI-CMS Phone Prompting Scripts