2022 National Survey on Drug Use and Health

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

Overview

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. The 2022 NSDUH will represent the 42nd in the series.

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 abuse and mental health; 2) monitoring substance abuse and mental health trends and patterns; 3) identifying licit and illicit substances being 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 abuse 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 abuse prevention, treatment, and rehabilitation programs.

The 2022 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 2022 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 2022 NSDUH sample will be

allocated to age groups as follows: 25 percent 12 to 17, 25 percent 18 to 25, and 50 percent 26 or older. More details on the sample design can be found in Section B.1 and in Attachment A (Sample Design).

Unlike previous NSDUHs, a hybrid address-based sampling (ABS) design will be implemented for the 2022 NSDUH. 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.

For further reference, a detailed summary of the planned 2022 hybrid ABS design is included in Attachment A, Sample Design.

As certain parts of the United States likely reduce COVID-19 restrictions in 2022, NSDUH in-person data collection will proceed where possible. However, to ensure sufficient data are collected to produce nationally representative estimates for the 2022 survey, NSDUH will continue to employ a mix of in-person and web-based modes of administration. If the COVID-19 pandemic subsides to such levels to allow in-person data collection to resume nationwide, SAMHSA may reassess that multimode data collection model as part of the 2022 NSDUH. Regardless of mode, the content of the interview questionnaire administered to respondents is identical and will be combined for analysis and reporting.

In those areas where in-person data collection is permitted, NSDUH protocols, processes, and materials will continue to reflect the need to ensure the safety of respondents and field interviewers (FIs) with respect to COVID-19 as directed – after initial implementation of such measures beginning in October 2020 – which include equipping FIs with personal protective equipment (PPE), such as masks, gloves, hand sanitizer, etc. for use during data collection.

CBHSQ must also periodically update aspects of NSDUH to reflect changing substance use and mental health issues and to continue producing current data. For the 2022 NSDUH the following changes from 2021 are planned: 1) replacing the tobacco module with a redesigned nicotine module that includes questions about vaping and eliminates outdated terminology; 2) revising the marijuana module to include questions about the use of CBD, update questions on the mode of administration, and eliminate outdated terminology and includes changes to the market information for marijuana questions; 3) redesigning the adult and youth mental health services utilization modules into one Mental Health Service Utilization model to remove questions with outdated terminology and include questions about newer treatments with recent increases in popularity; and 4) replacing the drug treatment module with a redesigned alcohol and drug treatment module that includes questions about newer treatments and those that have increased in popularity, as well as eliminating outdated terminology and reducing respondent burden.

For further reference, a detailed summary of all specific NSDUH questionnaire changes for 2022 is included on page i of Attachment B, CAI Questionnaire.

2. Purpose and Use of Information

The purpose of the 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. as well as for each state. 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 Centers for Disease Control and Prevention (CDC), ONDCP, 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 abuse research, prevention, and treatment 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 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 2022 questionnaire is presented in Section B.2.

3. Use of Information Technology

In-Person Data Collection

NSDUH data will be collected in a face-to-face interview setting in respondents' homes using laptop computers. 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 FIs 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.

For 2022, 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 in 2022. 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 and allow 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 C). 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.

4. Efforts to Identify Duplication

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 incidence and prevalence estimates, especially 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 can have considerable effects on the results, especially with items that are prone to social desirability bias (Groves, 1989). NSDUH is conducted in the household 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 prevalences 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,

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 and intentional injuries; 2) tobacco use; 3) alcohol and other drug use; 4) sexual behaviors that contribute to unintended pregnancy and sexually transmitted diseases; 5) unhealthy 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. The students 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. Like MTF, this study is targeted at a different population and collects data in a different setting than NSDUH. Possibly 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.

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 350,000 adults are interviewed each year. National data are calculated using a median score across states.

NHIS is an in-person household survey that has been conducted since 1957. Sample sizes are relatively large. For example, the 2017 NHIS public use file had data for 32,617 households containing 78,132 individuals. Sample sizes for the Sample Adult Core and Sample Child Core components of the survey were 26,742 and 8,845, respectively (National Center for Health Statistics, 2018).

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 ACASI 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.

Sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Epidemiologic Survey on Alcohol and Alcohol Related Conditions (NESARC) is another study that contains 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 (Grucza et al., 2007).

Some national mental health surveys were conducted several years ago. 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.

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 clinical follow-up 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.

5. Involvement of Small Entities

NSDUH does not involve small businesses or other such entities.

6. Consequences If Information Is Collected Less Frequently

The existence of substance abuse 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 abuse;

2) the continued demand within SAMHSA, ONDCP, and other federal agencies for data on the nature and size of the nation's substance abuse 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.

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

This information collection for NSDUH fully comply with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

A Federal Register notice was published on April 05, 2021 (86 FR 17614). No public comments were received on the 2022 NSDUH.

Appendix A of this Supporting Statement contains a listing of current consultants on NSDUH.

There are no unresolved issues resulting from these consultations.

9. Payment to Respondents

Adult respondents (aged 18 or older) and youth respondents (aged 12 to 17) are given $30.00 upon completion of the NSDUH 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 2003-2021 NSDUHs. The weighted overall response rates for 2001-2019 appear in Table 1. The 2021 NSDUH 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 C); Question & Answer Brochure (Attachment D); Tablet Screening Video Scripts (Attachment E); Contact Cards (Attachment F); Study Description (Attachment G); Introduction and Informed Consent Scripts (Attachment H);

Screening Questions (Attachment I); Unable-to-Contact and Controlled Access Letters (Attachment J); Refusal Letters (Attachment K); and Interview Incentive Receipt (Attachment L).

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%

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%

10. Assurance of Confidentiality

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 M) 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 2022 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

Several procedures ensure that respondents' rights are protected during in-person data collection. First, the FI introduces himself or herself and the study using the Introduction and Informed Consent Scripts (Attachment H), reading the scripted text 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 N). As part of the process for obtaining informed consent, respondents are given a Study Description (Attachment G), 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

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.

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 O) 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 (Attachment P). FIs also complete CIPSEA and project training on ensuring respondent confidentiality and will have signed a notarized Data Collection Agreement (Attachment P) 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 field interviewers but has been updated to incorporate text specific to the web mode administration.

This text (included in Attachment WEB-1) 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 Study Description (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 first 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-3.

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.

11. Questions of a Sensitive Nature

Many of the NSDUH 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 H, 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 (adults only), 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.

12. Estimates of Annualized Hour Burden

For the 2022 NSDUH, the sample has been designed to yield approximately 67,507 completed interviews combined across both modes of administration. It will be necessary to sample approximately 300,671 households and complete approximately 168,673 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 2020 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 2020 took about 60 minutes to administer, on average. Since there are only a few changes to the 2022 questionnaire, it is estimated that the average amount of time required to administer (or self-administer for the web mode) the 2022 CAI Questionnaire (Attachment B) will also be approximately 60 minutes.

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.

Previous experience indicates that approximately 60 percent of all in-person screenings will result in one of those six screening codes. An approximate five percent random sample of all such screening codes will be selected for verification follow-up.

The data collection field period for the 2022 NSDUH is 12 months, spanning the period from January through December 2022. The annualized estimated respondent burden for the 2022 NSDUH is shown in Table 3.1. The hourly wage of $19.13 was calculated based on weighted data from the 2019 NSDUH and respondents' reported personal annual income.

Table 3.1 Annualized Estimated Respondent Burden for 2020 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	168,673	1	168,673	0.083	14,000	$19.13	$267,820
Interview	67,507	1	67,507	1.000	67,507	$19.13	$1,291,409
Screening Verification	4,068	1	4,068	0.067	273	$19.13	$5,222
Interview Verification	8,230	1	8,230	0.067	551	$19.13	$10,541
Total	248,478		248,478		82,331		$1,574,992

13. Estimates of Annualized Cost Burden to Respondents

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

14. Estimates of Annualized Cost to the Government

Total costs associated with the 2022 NSDUH are estimated to be $69,436,795 over a 48-month contract performance period. Of the total costs, $59,646,635 are for contract costs (e.g., sampling, data collection, processing, reports) and approximately $7,266,300 represents CBHSQ costs to manage/administrate the survey. The annualized cost is approximately $17,359,199.

15. Changes in Burden

Currently, there are 219,105 total burden hours in the OMB inventory. SAMHSA is requesting 82,331 burden hours for 2022. This decrease of 136,030 burden hours is due to accumulation of combined burden hours from the 2019 and 2020 NSDUH ICR submissions.

The revised modules on nicotine, marijuana, mental health service utilization, and alcohol and drug treatment for 2022 will not result in a significant increase in respondent burden because these questions are closed-ended which typically take an average 10 seconds to administer, so most respondents will only see a minor increase.

16. Time Schedule, Publication and Analysis Plans

Plans for the 2022 survey data involve six major types of data products: 1) First Findings 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 2022 NSDUH.

1) First Findings Report (September 2023). 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 trends 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 2019 First Findings Report was released in September 2020.

2) State Findings (December 2023/February 2024). 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 2021-2022 state small area estimates, significant tests of change between the 2020-2021 and the 2021-2022 state population percentages will be included**.**

3) Substate Findings (April 2024/June 2024). Data from the combined 2020, 2021, and 2022 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 2020-2022 substate small area estimates, significant tests of change between the 2018-2020 and the 2020-2022 substate region population percentages will be included.

4) Public-Use Data File (PUF) (October 2023). 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 eleven pair-year data files, 2002-2003, 2004-2005, 2006-2007, 2008-2009, 2010-2011, 2012-2013, 2014-2015, 2015-2016, 2016-2017, 2017-2018, and 2018-2019. 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 2022 NSDUH

Activity	Time Frame
Design and select area frame sample	January 2021 to March 2021
Prepare field Segment Kits	February 2021 to May 2021
Prepare for and conduct field staff training	February 2021 to January 2022
Recruit/train field staff to list SDUs	May 2021 to July 2021
Conduct field listing and subsequent keying of SDUs	August 2021 to January 2022
Program the screening and interview instruments	August 2021 to October 2021
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2021 to January 2022
Conduct screenings and interviews	January 2022 to December 2022
Conduct full-year data processing and file preparation	January 2023 to March 2024
Prepare Trend Tables and Special Tabulations: • Finalize Shells • Finalize Annual Tables	 March 2023 June 2023
Prepare Raw Data Files	May 2023
Release Preliminary Weighted Data Files	May 2023
Finalize Sampling Error Report	July 2023
Prepare State Findings	August 2023 to March 2024
Release Final Analytic Data File and documentation	September 2023
Publish First Findings Reports	September 2023
Release Public Use Data File	October 2023
Publish Methodological Resource Book	March 2024

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.