

2019 National Survey on Drug Use and Health

SUPPORTING STATEMENT

In this revision request, OMB approval is being sought to:

- Conduct 2020 NSDUH using the questionnaire that was approved for 2019 with the following changes: questions about vaping anything and vaping nicotine or tobacco, questions about synthetic marijuana and synthetic stimulants; questions to measure marijuana withdrawal symptoms, prescription tranquilizer misuse withdrawal symptoms and craving for all substances in concordance with the Diagnostic and Statistical Manual of Mental Disorders, fifth edition criteria (*DSM-5*); minor revisions to the marijuana marketplace module; and 4) other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.
- Continue to redesign the NSDUH via 2020 Clinical Validation Study and the 2020 Field Test Nonsubstantive change requests will be submitted to request permission to make subsequent minor modifications to the questionnaire(s) and to conduct methodological testing.

A. JUSTIFICATION

1. Circumstances of Information Collection

Overview

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for an extension 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 2019 NSDUH will represent the thirty-ninth in the series. The 2020 NSDUH will represent the 40th 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.

For the sample design, the 2019 and 2020 NSDUH will continue to use the same design implemented since the 2014 survey, which provides data at both the national level and the state level. The survey's sample design will 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 2019 and 2020 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 2019 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, 2019 and 2020).

CBHSQ must periodically update aspects of NSDUH to reflect changing substance use and mental health issues and to continue producing current data. For the 2020 NSDUH main study the following changes from 2019 are planned: 1) the addition of lifetime and recency questions about vaping anything and vaping nicotine or tobacco; the addition of lifetime and recency questions on synthetic marijuana and synthetic stimulants; 2) the addition of questions in concordance with the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition criteria (*DSM-5*) to measure the occurrence of marijuana withdrawal symptoms, occurrence of prescription tranquilizer misuse withdrawal symptoms and occurrence of craving for all substances; 3) minor revisions to the marijuana marketplace module; and 4) other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

By including these new questions in NSDUH, estimates may be generated on the use of these substances among the general population and allow SAMHSA to provide national-level estimates among adults and adolescents on the use of vaping, synthetic marijuana, and synthetic stimulants. In addition, because NSDUH collects demographic, socioeconomic, and health information about each respondent, the inclusion of these questions would permit a more detailed understanding of factors associated with their use.

The new questions on craving for all substances and withdrawal for marijuana/cannabis were added to the 2020 NSDUH main study to reflect the updated *DSM-5* diagnostic criteria for substance use disorders. Questions measuring withdrawal for tranquilizers have been added to ensure SUD for tranquilizers is accurately assessed as well.

The marijuana marketplace module (originally dropped in the 2015 redesigned questionnaire) was reinserted in the NSDUH main study questionnaire starting in 2018 at the request of the White House Office of National Drug Control Policy (ONDCP) but

was unchanged from the version previously used in the 2014 NSDUH. (This module was not part of the NSDUH questionnaire from 2015-2017.) This module consists of a series of questions that seek to gather data such as the location, quantity, cost and type of marijuana being purchased across the nation. Slight revisions have been made to this module for 2020 to reflect that marijuana can now be purchased from a retail store or dispensary.

For further reference, a detailed summary of all specific NSDUH questionnaire changes for 2019, as compared with the 2018 NSDUH, is included in Attachment Z (2019). A detail summary of all specific NSDUH questionnaire changes for 2020, as compared with the 2019 NSDUH is included in Attachment Z (2020).

Additional information regarding the questionnaire and sample design for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

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.

An overview and description of the questionnaire structure and content areas covered by the 2019 questionnaire are provided in Attachment AA (2019) and for the 2020 questionnaire in Attachment AA (2020). For the 2019 main study questionnaire, the full set of questions are presented in Attachment B (2019) and for 2020 main study questionnaire in Attachment B (2020).

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 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 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.

To look specifically at depression, the 2004 NSDUH introduced two depression modules—one for adults and one for youth. The data collected focus on lifetime and past year prevalence of major depressive episodes, past year treatment for it, and its severity and impact on functioning. These data are used to obtain the prevalence and need for treatment of depression in the U.S. and will allow further research into the interaction between depression and drug use. These modules were included in the 2005-2018 NSDUHs, and will be included in the 2019 instrument as well. A detailed discussion of the 2019 questionnaire is presented in Section B.2.

Changes

NSDUH must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data. For the 2020 NSDUH the following changes are planned: 1) the addition of lifetime and recency questions about vaping anything and vaping nicotine or tobacco); the addition of lifetime and recency on synthetic marijuana and synthetic stimulants; 2) the addition of questions in concordance with the *DSM-5* to measure the occurrence of marijuana withdrawal symptoms, occurrence of prescription tranquilizer misuse withdrawal symptoms and occurrence of craving for all substances; 3) minor revisions to the marijuana marketplace module; and 4) other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

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Additional information regarding the purpose and use of information for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

3. Information Technology Use

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 field interviewers (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 2019 and 2020, 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. Following the integration of the Speech Platform software into all NSDUH questionnaires since 2015, there were no reported problems with the pronunciation of any words or phrases produced by the TTS voices in English or Spanish.

NSDUH will continue to use hand-held computers to conduct household screening interviews in 2019. 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.

A 7-inch touch screen Android tablet computer, used on NSDUH since 2015, will be used again for household screenings in 2019. This device will be used for screening, interview respondent selection, answering FI observation questions, and case management. The light-weight, ultra-book laptops, also used on NSDUH since 2015, will be used for 2019. These have the advantage of being easy for FIs to transport in the field while providing ample processing power for the necessary computer programs. Because these laptops have solid state drives, they are more durable and reliable than previous generations of NSDUH data collection laptops.

For 2020, as part of the standard equipment maintenance lifecycle, all NSDUH FIs will be using new computer equipment to complete screenings and interviews. The new equipment is very similar to those models used from 2015-2019. In addition to a new laptop for interview administration, a touch-screen Android tablet computer will be used for screening, interview respondent selection and answering FI observation questions.

These have the advantage of being easy for FIs to transport in the field while providing ample processing power for the necessary computer programs. Because these laptops have solid state drives, they are more durable and reliable than previous generations of NSDUH data collection laptops.

Also, these 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. In addition, 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.

Additional information regarding information technology use for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

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 abuse as provided by NSDUH. NSDUH is the only survey of substance use in the U.S. with a sample size capable of producing high-quality national and separate state incidence and prevalence estimates, especially by detailed demographic variables. No duplication of effort has been identified.

While several other surveys and data systems collect information on substance use, abuse, and dependence, there are important methodological differences between these surveys and NSDUH, which have implications on estimates of substance use prevalence. For example, the 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 is a school-based survey of 8th, 10th, and 12th graders that includes an ongoing panel study from each graduating class conducted by mail. 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, the MTF does not survey dropouts, a group that NSDUH has shown to have higher rates of illicit drug use (Gfroerer, Wright, & Kopstein, 1997).

It is also important to note that MTF conducts self-administered surveys in a school setting and by mail. 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 the 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 the CDC's Youth Risk Behavior Surveillance System (YRBSS), which biennially measures the prevalence of six priority health risk behavior categories: (a) behaviors that contribute to unintentional and intentional injuries; (b) tobacco use; (c) alcohol and other drug use; (d) sexual behaviors that contribute to unintended pregnancy and sexually transmitted diseases; (e) unhealthy dietary behaviors; and (f) 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. Like the 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 the YRBS are generally much higher than those from the 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.

Another study that collects data on health-related behaviors is the Behavioral Risk Factor Surveillance System (BRFSS). The BRFSS is an annual, state-based telephone survey of the civilian, noninstitutionalized adult population aged 18 or older and is sponsored by the 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.

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 whereas 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, the NESARC was designed to make inferences for persons aged 18 or older and is conducted in waves (2001/2002, 2004/2005 and 2012/2013). Also, the NESARC was designed to be a longitudinal survey, whereas NSDUH provides annual cross-sectional data. Another methodological difference between the two surveys is that sensitive questions in NSDUH are self-administered via ACASI whereas the 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).

Clinical Validation Study

CBHSQ is in contact with all major federal health survey managers and is aware of no other efforts to assess how potential respondents may react to questionnaire revisions to the NSDUH SUD module based on the *DSM-5* rather than the *DSM-IV*. To date, no duplication of effort has been identified.

Field Test

CBHSQ is in contact with all major Federal health survey managers and is aware of no other field tests to assess how changes made to the NSDUH incentives, respondent materials, screening and interview questionnaire and data collection procedures might affect reporting on the NSDUH. To date, no duplication of effort has been identified.

5. **Involvement of Small Entities**

This survey 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.

Clinical Validation Study

The CVS data collection is designed to assess the validity of revised questions on SUD prior to their inclusion in field tests in 2020 and 2022, and then their potential inclusion in the NSDUH main study. To meet this deadline, the CVS must conclude by June 2020 so results can be analyzed, and the revised SUD module questions can be included in these future tests/studies. The CVS is a one-time collection and will not be repeated.

Field Test

The FT data collection is designed to test for possible effects on data quality (as measured by outcomes such as unit nonresponse, item nonresponse, and survey response), questionnaire timing, data collection efficiency, and difference in reporting of substance use or mental health items on estimates. The FT is essential for providing a thorough examination of these changes prior to their deployment on the main study NSDUH. The FT 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 fully complies with 5 CFR 1320.5(d)(2).

8. **Consultation Outside the Agency**

A Federal Register notice was published on November 19, 2018 (83 FR 58267). 0 public comment were received.

Appendix A of this Supporting Statement contains a listing of current consultants on the main NSDUH questionnaire. SAMHSA received feedback on the medication-assisted treatment (MAT) for opioids and alcohol question from ONDCP, NIDA, and NIAAA. Appendix B of this Supporting Statement contains the feedback and response.

There are no unresolved issues resulting from these consultations.

2020 NSDUH, Clinical Validation Study, and Field Test

A Federal Register notice published on June 12, 2019 (84 FR 27341) for the NSDUH 2020 main study also included the CVS and the FT. One public comment was received, see Attachment X. See Attachment Y for SAMHSA’s response.

Additional information regarding the current consultants for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

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 in cash upon completion of the full interview. 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 2003-2018 NSDUHs. The weighted overall response rates for 2001-2017 appear in Table 1. The 2019 and 2020 NSDUH call for the same incentive plan, whereby a \$30.00 incentive will be given to respondents upon completion of the 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, Controlled Access, and Call-Me 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%

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%

Additional information regarding payments to respondents for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

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 2018 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.

Several procedures ensure that respondents’ rights are protected. 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. This statement will appear in the Showcard Booklet (Attachment N) and is read aloud to each interview respondent. 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 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, except in rare instances where a 17-year-old lives independently from his or her parent or guardian (in which case the 17-year-old provides his or her own consent), when the youth is selected for the 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 in the respondent's home 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 a headset 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 that no one can see the responses until after the data are transmitted, processed, and aggregated by the Contractor in a FIPS-Moderate environment.

To further ensure confidentiality, the respondent's name, address, or other identifying information are never noted. The one exception is the Quality Control Form (Attachment Q), which the respondent is asked to voluntarily complete at the end of the interview. The FI explains the procedures in advance, asking the respondent to record his or her phone number and current address on the Quality Control Form and then place the form in an envelope and seal the envelope. The Quality Control Forms are mailed directly to the Contractor's office in North Carolina and used only for verification purposes.

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.

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 Quality Control Forms are destroyed, thus eliminating records of sample dwelling unit (SDU) addresses. 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, the most recent Privacy Impact Assessment (PIA), approved and signed by HHS in May 2017, covers the 2019 NSDUH (since this is processed annually).

Additional information regarding the assurance of confidentiality for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo.

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, improve the privacy of data collected on sensitive issues. As a part of the interview introduction, the FI informs the respondent why the information is necessary, indicates who sponsors the study, requests consent to conduct an interview, and explains the procedures that ensure confidentiality. As noted in section A.10, for respondents between the ages of 12 and 17—except in rare instances where a 17-year-old lives independently without a parent or guardian and provides his or her own consent—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 that 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 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 using Computer Assisted Interviewing (CAI) 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

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.

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.

Additional information regarding questions of a sensitive nature for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo.

12. Estimates of Annualized Hour Burden

For the 2019 NSDUH, the sample has been designed to yield approximately 67,507 completed interviews. It will be necessary to sample approximately 219,305 households and complete approximately 137,231 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 2018 screening process, administration of the screening questions is expected to take an average of five minutes per SDU.

Initial timing data indicate the NSDUH questionnaire used in 2018 took about 60 minutes to administer, on average. Since there are only a few changes to the 2019 questionnaire, it is estimated that the average amount of time required to administer the 2019 CAI Questionnaire (Attachment B) will also be approximately 60 minutes, including two minutes for the Quality Control Form (Attachment Q).

Screening and interview verification 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 screening codes that do not result in a respondent being selected for an 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 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 2019 NSDUH is 12 months, spanning the period from January through December 2019. The annualized estimated respondent burden for the 2019 NSDUH is shown in Table 3.1. The hourly wage of \$17.60 was calculated based on weighted data from the 2016 NSDUH and respondents' reported personal annual income.

Table 3.1 Annualized Estimated Respondent Burden for 2019 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	137,231	1	137,231	10.083	11,390	\$17.60	\$200,464
Interview	67,507	1	67,507	71.000	67,507	\$17.60	\$1,188,123
Screening Verification	4,116	1	4,116	60.067	276	\$17.60	\$4,858
Interview Verification	10,126	1	10,126	60.067	678	\$17.60	\$11,933
Total	137,231		218,980	80	79,851		\$1,405,378

For the 2020 NSDUH, the sample has been designed to yield approximately 69,007 completed main study interviews. It will be necessary to sample approximately 233,248 households and complete approximately 143,255 screenings to obtain the requisite number of main study 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 2019 screening process, administration of the screening questions is expected to take an average of five minutes per SDU.

Initial timing data indicate the NSDUH questionnaire used in 2019 took about 60 minutes to administer, on average. Since there are only a few changes to the 2020 questionnaire, it is estimated that the average amount of time required to administer the 2020 CAI Questionnaire (Attachment B) will also be approximately 60 minutes, including two minutes for the Quality Control Form (Attachment Q).

Screening and interview verification 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 screening codes that do not result in a respondent being selected for an 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 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 2020 NSDUH main study is 12 months, spanning the period from January through December 2020. The annualized estimated respondent burden for the 2020 NSDUH is shown in Table 3.2. The hourly wage of \$18.48 was calculated based on weighted data from the 2017 NSDUH and respondents' reported personal annual income.

Table 3.2 Annualized Estimated Respondent Burden for 2020 NSDUH Main Study

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	143,255	1	143,255	50.083	11,890	\$18.48	\$219,727
Interview	69,007	1	69,007	71.000	69,007	\$18.48	\$1,275,249
Screening Verification	4,348	1	4,348	80.067	291	\$18.48	\$5,378
Interview Verification	10,351	1	10,351	10.067	694	\$18.48	\$12,825
Total	143,255		226,961		81,882		\$1,513,179

For the CVS, the sample has been designed to yield approximately 826 completed clinical interviews. It will be necessary to supplement the NSDUH sample with approximately 1,500 additional interviews to obtain the requisite number of CVS clinical interviews. Based on previous experience with the NMHS and MHSS, administration of the follow-up clinical interview questions is expected to take an average of 50 minutes per respondent.

The data collection field period for the 2020 CVS is six months, spanning the period from January through June 2020. The annualized estimated respondent burden for the CVS is shown in Table 3.3. The hourly wage of \$18.48 was calculated based on weighted data from the 2017 NSDUH and respondents' reported personal annual income.

For the CVS, approximately 23 CIs will be hired to conduct the follow-up clinical interviews. Minimum CI credentials require either enrollment in a third year doctoral-level psychology program or a doctoral degree in clinical or counseling psychology, a medical degree with a specialty in psychiatry, or an advanced degree in a related field such as clinical social work.

In addition to attending a training session prior to CVS data collection, all CIs will be required to complete and pass a certification interview before being assigned cases for the study. The certification interview will involve conducting the CVS interview over the telephone with a volunteer respondent. This process will require CIs to properly administer the instrument and follow study protocols and is also expected to take an average of 50 minutes per respondent.

Each CI will get up to three opportunities to successfully pass the certification interview process. That will require a maximum of 70 respondents to volunteer for and complete a certification interview. Certification respondents will be adult and youth volunteers recruited from outpatient treatment centers and support groups who report alcohol, marijuana and/or illegal drug use in the past 12 months who have also received some form of treatment during that time.

Table 3.3 Annualized Estimated Respondent Burden for 2020 CVS

Instrument	No. of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Hourly wage rate	Total hour cost
Follow-up Clinical Certification	70	1	70	0.83	58	\$18.48	\$1,072
Follow-up Clinical Interview	826	1	826	0.83	686	\$18.48	\$12,677
Total	896		896		744		\$13,749

During FT data collection from August through November 2020, conducted separately from ongoing 2020 NSDUH main study data collection at that time, screenings will be completed with approximately 8,110 English-speaking respondents in the contiguous United States. (Alaska and Hawaii are excluded from the FT to control study costs.) From those screenings, approximately 4,000 respondents, as representatives of the civilian, noninstitutional population aged 12 years old or older, are expected to complete a FT interview using the revised questionnaire and materials.

The total annual burden estimate for the FT is shown below in Table 3.4

Table 3.4 Annualized Estimated Burden for Redesign Field Test

Instrument	No. of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	8,110	1	8,110	0.083	673
Interview	4,000	1	4,000	1.000	4,000
Screening Verification	246	1	246	0.067	17
Interview Verification	600	1	600	0.067	40
Total	8,110		12,956		4,730

Table 3.5. Annualized Estimated Respondent Burden for the 2019 and 2020 NSDUH, 2020 CVS and 2020 Redesign Field Test

Instrument	No. of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Hourly wage rate	Total hour cost
Household	288,596	1	288,596	0.249	71,860	\$18.48	\$1,327,973

Screening							
Interview	140,514	1	140,514	0.00	140,514	\$18.48	\$2,596,698
Screening Verification	8,710	1	8,710	0.201	1,755	\$18.48	\$32,358
Interview Verification	21,077	1	21,077	0.201	4,235	\$18.48	\$78,281
Follow-up Clinical Certification	70	1	70	0.83	58	\$18.48	\$1,072
Follow-up Clinical Interviews	826	1	826	0.83	686	\$18.48	\$12,677
Total	288,666		459,793		219,105		\$4,049,059

13. Estimates of Annualized Cost Burden to Respondents

There are no capital, startup, operational, or maintenance costs to respondents for the 2019 NSDUH, 2020 NSDUH, 2020 CVS, or the 2020 Redesign Field Test.

14. Estimates of Annualized Cost to the Government

Total costs associated with the 2019 NSDUH are estimated to be \$61,978,833 over a 48-month contract performance period. Of the total costs, \$54,850,333 are for contract costs (e.g., sampling, data collection, processing, reports), and approximately \$7,128,500 represents CBHSQ costs to manage/administrate the survey. The annualized cost is approximately \$15,494,708.

Total costs associated with the 2020 NSDUH are estimated to be \$69,436,795 over a 48-month contract performance period, including the CVS. Of the total costs, \$62,170,495 are for contract costs (e.g., sampling, data collection, processing, reports) – \$59,509,103 for the main study and \$2,661,392 for the CVS – and approximately \$7,266,300 represents CBHSQ costs to manage/administrate the survey. The annualized cost is approximately \$17,359,199.

Additional information regarding estimates of annualized cost to the government for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

15. Changes in Burden

Currently, there are 79,851 total burden hours in the OMB inventory. SAMHSA is requesting 81,882 burden hours for the main study.

The inclusion of the additional questions on vaping and synthetics for 2020 will not result in a significant increase in main study 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.

Additional information regarding changes in burden for the 2020 Clinical Validation Study is included in 2019 OMB addendum – CVS memo and for the 2020 Field Test is included in the 2019 OMB addendum – FT memo.

16. Time Schedule, Publication and Analysis Plans

Plans for the 2019 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) analytic reports; 4) Public Use Data File (PUF); 5) Restricted Use Data File (R-DAS); and 6) Data Portal Data File System. Descriptions of major products, as well as approximate delivery dates follow. Table 4a includes a schedule for the 2019 NSDUH and Table 4b includes a schedule for the 2020 NSDUH.

Plans for the 2020 survey data involve one additional data product: the Restricted-use Data Centers.

1) Overall Reports

First Findings Reports (September 2020 and September 2021). Prior to 2014, RTI produced one or two major national reports annually from the most current NSDUH data: a national findings report that focused on issues related to substance use, and (since the 2009 NSDUH) a mental health findings report that focused on mental health issues. Since 2014, RTI has worked with SAMHSA to produce reports focused on specific topics at the national level and a web-only methodological summary. National reports have covered 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.

2) State Findings

State Findings (December 2020 and December 2021). Data from the combined 2018 and 2019 NSDUHs will be used to provide state estimates (for the 50 states and the District of Columbia) for select substance use and mental health outcomes. These estimates will be produced using SAE methodology. Along with the 2018-2019 SAEs, significant tests of change between the 2016-2017 and the 2017-2018 SAEs will be included.

Data from the combined 2019 and 2020 NSDUHs will be used to provide state estimates (for the 50 states and the District of Columbia) for select substance use and mental health outcomes. These estimates will be produced using SAE methodology. Along with the 2019-2020 SAEs, significant tests of change between the 2016-2017 and the 2017-2018 SAEs will be included.

3) Analytic Reports

Analytic Reports. Additional data analyses and special analytical papers will be produced and released as part of the CBHSQ Analytic Series, or A report series. Additional topics and dates of completion for these reports are currently undetermined. Supplemental tables involving population projections for specified licit and illicit substances also will be produced and made available to those requesting such information.

4) Public Use Data File (PUF)

Public Use Data File (October 2020 and October 2021). 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

Restricted-Use Data Files (Ongoing). The R-DAS is a combination of various Analytic Data File variables that are continuous across study years. There are currently nine pair-year data files, 2002-2003, 2004-2005, 2006-2007, 2008-2009, 2010-2011, 2012-2013, 2014-2015, 2015-2016 and 2016-2017. Similarly, there are four 4-year files, 2002-2005, 2006-2009, 2010-2013 and 2014-2017, two eight year files, 2002-2009 and 2006-2013, one 10-year file, 2002-2011, 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) Data File for the Data Portal Data File System

Data Portal Data Files (Ongoing). The Data Portal is managed by SAMHDA. RTI provides Analytic Data Files and Codebooks to SAMHDA for use in their system. The system provides a list of 'base' variables that are included for SAMHSA agents that apply for data. The Base variables are variables that exist on the PUF in the form that exists on the restricted use Analytic file (i.e., no additional treatment to avoid disclosure risk). In addition to the Base Variables, all other Analytic variables are eligible for analysis but agents must apply to use them. SAMHSA then determines whether the requested variables will be added to the agent's data file.

7) Restricted-use Data Centers (RDC)

Restricted-use Data Centers (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 4a. Project Schedule for the 2019 NSDUH

Activity	Time Frame
Design and select area frame sample	January 2018 to March 2018
Prepare field Segment Kits	February 2018 to May 2018
Prepare for and conduct field staff training	February 2018 to January 2019
Recruit/train field staff to list SDUs	March 2018 to May 2018
Conduct field listing and subsequent keying of SDUs	April 2018 to January 2019
Program the screening and interview instruments	August 2018 to October 2018
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2018 to January 2019
Conduct screenings and interviews	January 2019 to December 2019
Conduct full-year data processing and file preparation	January 2020 to March 2021
Prepare Trend Tables and Special Tabulations: <ul style="list-style-type: none"> • Finalize Shells • Finalize Annual Tables 	March 2020 June 2020
Prepare Raw Data Files	May 2020
Release Preliminary Weighted Data Files	May 2020
Finalize Sampling Error Report	July 2020
Prepare State Findings	August 2020 to March 2021
Release Final Analytic Data File and documentation	September 2020
Publish First Findings Reports	September 2020
Publish Mental Health Findings	November 2020
Release Public Use Data File	October 2020
Publish Methodological Resource Book	March 2021

Table 4b. Project Schedule for the 2020 NSDUH

Activity	Time Frame
Design and select area frame sample	January 2019 to March 2019
Prepare field Segment Kits	February 2019 to May 2019
Prepare for and conduct field staff training	February 2019 to January 2020
Recruit/train field staff to list SDUs	March 2019 to May 2019
Conduct field listing and subsequent keying of SDUs	April 2019 to January 2020
Program the screening and interview instruments	August 2019 to October 2019
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2019 to January 2020
Conduct screenings and interviews	January 2020 to December 2020
Conduct CVS follow-up clinical interviews	January 2020 to June 2020
Conduct full-year data processing and file preparation	January 2021 to March 2022
Prepare Trend Tables and Special Tabulations: <ul style="list-style-type: none"> • Finalize Shells • Finalize Annual Tables 	March 2021 June 2021
Prepare Raw Data Files	May 2021
Release Preliminary Weighted Data Files	May 2021
Finalize Sampling Error Report	July 2021
Prepare State Findings	August 2021 to March 2022
Release Final Analytic Data File and documentation	September 2021
Publish First Findings Reports	September 2021
Release Public Use Data File	October 2021
Publish Methodological Resource Book	March 2022

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.