

2015 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 2015 NSDUH will represent the thirty-fifth 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 2015 NSDUH will continue to use the same design implemented for 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 2015 sample design will also include the same age group allocation implemented in 2014. To accurately estimate drug use and related mental health measures among the aging drug use population, the 2015 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. Finally, in order to facilitate a possible transition to an address-based sample (ABS) design in the future, the 2014 and 2015 sample designs include an additional stage of selection (Census block groups). More details on the sample design can be found in Section B.1 and in Attachment A (Sample Design).

While the sample design will remain the same for 2015, CBHSQ must periodically update other aspects of the NSDUH to reflect changing substance use and mental health issues and to continue producing current data. CBHSQ has such plans for the 2015 NSDUH survey year to achieve two goals: 1) revise the questionnaire to address changing policy and research data needs, and 2) modify the survey methodology to improve the quality of estimates and the efficiency of data collection and processing.

Planned revisions for the 2015 NSDUH to the questionnaire, methodology and materials, including an assessment of new computer equipment, were initially tested in 2012 as part of the NSDUH Questionnaire Field Test (QFT) (OMB No. 0930-0334), then further refined and tested again in 2013 during the NSDUH Dress Rehearsal (DR) (OMB No. 0930-0334). As such, changes described herein were successfully tested as part of the QFT and/or DR – unless otherwise noted. Attachments B and C (QFT Final Report, DR Final Report) provide detailed information about the questionnaire, procedures, materials and equipment tested in the two field tests.

Based on the successful outcome of these two field tests, major changes for the 2015 NSDUH from 2014 include, but are not limited to:

- added prescription drug images and electronic reference calendar to laptop screens as appropriate;
- updated questionnaire modules on prescription drugs;
- added new questions on sexual orientation;
- redesigned contact materials to maximize response rates;
- added new computer equipment for field interviewers (FIs) to manage and administer data collection.

Additional detail on all changes for 2015 is provided below.

Questionnaire Changes

In order to achieve CBHSQ's first goal of revising the questionnaire to address changing policy and data needs, the 2015 questionnaire changes include the following revisions:

- revised the educational attainment response categories;
- changed to a lower threshold of binge alcohol use for females (based on consumption of four or more drinks in a single occasion);
- created a new methamphetamine module;

- revised questionnaire modules for smokeless tobacco, hallucinogens, inhalants, prescription drugs, special drugs, consumption of alcohol, and health care; and
- revised back-end demographics questions.

Also, to aid respondent recall, the 2015 questionnaire will display images of prescription drugs and an electronic reference date calendar on the laptop screen when appropriate during the audio computer-assisted self-interviewing (ACASI) portion of the interview, as opposed to hard-copy versions of these items that are used for the 2014 NSDUH questionnaire administration.

Throughout cognitive testing and subsequent field tests prior to implementation of the 2015 NSDUH (detailed in Attachment D, Redesign Pretesting Summary Report), special attention was paid to modules that measure prescription drug misuse (also known as "nonmedical" use) because misuse of prescription psychotherapeutic drugs (i.e., pain relievers, tranquilizers, stimulants, or sedatives) is second only to marijuana in prevalence for substances other than tobacco and alcohol (CBHSQ, 2013). Misuse of prescription drugs is defined in the 2014 NSDUH as use of a drug that was not prescribed for the respondent or that the respondent took only for the experience or feeling it caused.

This redesign of the prescription drug modules was further prompted by challenges and issues associated with measurement of the concept of misuse, which were discussed in a NSDUH report on prescription drugs (Colliver, Kroutil, Dai, & Gfroerer, 2006). Additionally, some researchers have expressed concern that the phrase "for the experience or feeling it caused" may erroneously capture reports of legitimate use based on the intended effects of the drug, such as pain relief (Huang, Dawson, Stinson, Hasin, et al., 2006). Further, the 2014 NSDUH definition of misuse does not include the criterion of overuse of prescribed medication (e.g., use of medication in greater amounts or more often than prescribed); which is particularly important for prescription pain relievers. Therefore, the definition of misuse for the 2015 NSDUH will be revised to refer to use "in any way a doctor did not direct you to use it/them." Respondents will be presented with examples of use in any way not directed by a doctor, including (a) use without a prescription of one's own; (b) use in greater amounts, more often, or longer than told to take a drug; and (c) use in any other way not directed by a doctor.

Also, to address the information needs of the U.S. Food and Drug Administration (FDA) and the Office of National Drug Control Policy (ONDCP), questions about misuse of specific prescription drugs or related drugs with a common active ingredient will focus on misuse of these drugs in the 12 months prior to the interview. The NSDUH questionnaire prior to 2015 has asked about misuse of most specific prescription drugs in the lifetime period. Moreover, since the last major redesign of the prescription drug questions in NSDUH for the 1999 survey, several of the prescription drugs that are currently included in the interview—particularly for stimulants and sedatives—have been discontinued or are no longer legally available by prescription in the United States. New prescription drugs or new formulations also have been approved since the last major redesign, but the survey questions that are used for publishing estimates on the prevalence of prescription drug misuse do not explicitly include these newer drugs.

In order to meet the Secretary's goal to include sexual orientation questions in the 2015 NSDUH, two questions have been added to the ACASI section of the interview for adults. These questions were tested during the DR and closely resemble those fielded in the National Survey of Family Growth (NSFG) both in wording and structure.

The inclusion of questions on sexual orientation directly addresses objectives in Healthy People 2020. The Healthy People goal is to improve the health, safety, and well-being of lesbian, gay, bisexual, and transgender individuals. The specific objective addressed is: LGBT-1 (Developmental) Increase the number of population-based data systems used to monitor Healthy People 2020 objectives that include in their core a standardized set of questions that identify lesbian, gay, bisexual, and transgender (LGBT) populations.

NCHS thoroughly tested sexual identity (SI) questions in both ACASI and CAPI modes. NCHS found that there was no significant difference in the estimates of sexual minorities by mode and "no clear cut mode advantage to the collection of SI data" (Dahlhamer et al., 2013). The National Health Interview Survey (NHIS) does not currently have an ACASI section. When NHIS tested the SI questions, they were also testing their new ACASI mode. During the testing, NCHS experienced more breakoffs in their new ACASI mode compared to CAPI mode. It has not been established that the placement of the SI questions in either mode was the cause of this increase in breakoffs when compared to their current CAPI mode. The NSDUH has an established ACASI mode for sensitive questions with a current breakoff rate of less than one percent.

When item-nonresponse rates were examined in the NHIS pilot test, they were found to be generally comparable by mode (Dahlhamer et al., 2013). NSDUH tested a sexual attraction and sexual identity question in the 2013 Dress Rehearsal (OMB No. 0930-0334) within the ACASI mode and found that item non-response rates for these questions to be 0.2 and 0.3 percent, respectively. Although the sample size for this test was small (2,000 cases), these rates are considerably lower than the item non-response rates for the NSDUH income questions (approximately 3%), which are administered in CAPI mode.

For questions where respondents might view their responses as sensitive, there is substantial research that shows more truthful reporting in self-administered versus interviewer-administered modes. From the Tourangeau and Smith (1996) study on sexual behaviors, ACASI has become known as a valuable method for collecting accurate responses on sensitive questions, such as sexual behavior or substance use (de Leeuw, Hox, & Kef, 2003; Tourangeau & Yan, 2007; Turner et al., 1998). ACASI has been the standard for asking sensitive questions in the NSDUH since 1999. NCHS provided a similar rationale for testing the SI questions in ACASI mode:

While few studies have explored the effects of administration mode on reporting one's sexual identity, the much larger literature on sexual behavior suggests that the use of computer-assisted self-administered modes such as ACASI should lead to higher—and presumably more accurate-- levels of sexual minority reporting than interviewer-administered modes such as CAPI and CATI (Dahlhamer et al.,

2013, p. 10).

While NCHS found that ACASI was not an appropriate mode for most questions in their survey, they did not rule it out as a mode for the SI questions. Since NSDUH has an established ACASI section for sensitive questions, SAMHSA feels that the ACASI section of the questionnaire is the appropriate location for the SI questions. In addition, the National Survey of Family Growth (NSFG), also sponsored by NCHS, has SI questions similar those in the NSDUH and administers them in ACASI mode, providing the model that SAMHSA has followed.

A few other additional minor changes have been made to the questionnaire specifications for 2015 since testing the DR instrument in 2013:

- the term “Molly” has been added to questions about Ecstasy in the Hallucinogens module;
- questions about health insurance and income that were tested in an ACASI module in the QFT and DR were moved back to being administered by FIs. In the QFT and DR a higher item missing rate was found so they were moved back to the CAPI portion of interview;
- and other changes were made to logic and wording for consistency and to maximize respondent comprehension, along with other minor changes throughout the instrument to clarify intent.

Methodology Changes

With regard to CBHSQ’s second goal to update NSDUH methodology to improve the quality of the estimates and the efficiency of data collection, several changes are planned for 2015.

Revised respondent materials used during the DR will also be used for the 2015 NSDUH, including the Lead Letter (Attachment E) and the Question & Answer Brochure (Attachment F). The Lead Letter is mailed to respondents prior to being contacted by an FI and the Question & Answer Brochure is provided by FIs to respondents during the interview.

Also, all 2015 items will now reference the U.S. Department of Health and Human Services, rather than the U.S. Public Health Service, and any previous mention of the Contractor, Research Triangle Institute, will now be displayed as RTI International. These changes were made in order to improve the accuracy of the letter and revise the content in ways likely to have a positive influence on a respondent’s decision to participate.

Computer equipment for use by FIs that was tested during the QFT and DR will be used for the 2015 NSDUH, including a 7-inch touch screen Android tablet computer and a light-weight, ultra-book laptop. The tablet was tested in both the QFT and DR and will be used for screening, interview respondent selection, answering FI observation questions, and case management. The laptop was tested in the DR and will be used to conduct interviews in both English and Spanish.

Along with the new laptop, text to speech (TTS) software is being programmed and tested for implementation within the ACASI modules in 2015. TTS uses a computer-

generated voice to read text displayed on-screen, rather than relying on pre-recorded audio files from a human voice. This text will run dynamically in conjunction with the survey instrument and offers an opportunity for work process efficiencies and cost savings in NSDUH's ACASI software development. TTS will be implemented for the 2015 NSDUH unless there is a significant problem shown during testing. If TTS is not implemented, the current method of using pre-recorded audio files will be continued for the 2015 NSDUH.

In 2015, FIs will be able to utilize the multimedia capability of the touch screen tablet to play a short video for respondents (approx. 50 seconds run time) which provides a brief explanation of the study and why participation is important. The script for this video is included as Attachment G. Interviewers have the option to play this video for potential respondents as a tool for gaining cooperation. This video was not tested as part of the QFT or DR but we have no reason to believe that providing information to respondents in this manner will negatively impact participation.

Also contained within the tablet and new for 2015 is a parental introductory script. This script is to be read to a parent or guardian of a youth respondent before the FI speaks with that youth respondent about the NSDUH. This script will standardize the introductory conversations between FIs and parent/guardians before FIs speak with youths about taking part in NSDUH. This parental introductory script is included as Attachment H.

For further reference, a detailed summary of all specific NSDUH questionnaire and materials changes for 2015, as compared with the 2014 NSDUH, is included as Attachment I, 2015 NSDUH Questionnaire and Materials Changes.

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 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 2005-2014 NSDUHs, and will be included in the 2015 instrument as well. A detailed discussion of the 2015 questionnaire is presented in Section B.2.

3. Use of Information Technology

NSDUH data will be collected in a face-to-face interview setting in respondents’ homes using laptop computers. Interviews will be administered using 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 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 2015, questions administered via ACASI in the NSDUH interview will be read aloud to respondents using 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. During the initial evaluation of the Speech Platform software, there were no problems understanding any words or phrases produced by the TTS voices in English or Spanish.

The planned integration of TTS for 2015 is currently being programmed and tested with the expectation it will be implemented unless significant problems arise (in which case the ACASI modules will revert to the current method of using pre-recorded audio files read by a human voice).

As mentioned in Section A.1, NSDUH will continue to use hand-held computers to conduct household screening interviews in 2015. 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.

The iPAQ hand-held computers used for screening households since 2009 are being replaced for 2015. An alternative device, a 7-inch touch screen Android tablet computer, has been evaluated in the QFT and DR in 2012 and 2013 (OMB No. 0930-0334) and will be used for the 2015 NSDUH. This device will be used for screening, interview respondent selection, answering FI observation questions, and case management. The screening software was developed to function on an Android-based device, as opposed to

the iPAQ, which is Windows-based. This software takes advantage of the user interface that is inherent in Android devices, but otherwise functions largely the same as the iPAQ software. The Android tablet offers several advantages over the iPAQ including increased speed, readability, durability, functionality, and space for larger font. A new light-weight, ultra-book laptop, evaluated in the DR in 2013 (OMB No. 0930-0334) will be used for 2015. 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.

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 consistently 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 and 2004/2005). 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 FI-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 produces substantially higher rates of use of illicit drugs than NESARC (Gruca et al., 2007).

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.

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 April 24, 2014 (Vol. 79, page 22823) and one public comment was received. As shown in Attachment BB, the Campaign for Tobacco-Free Kids supports the implementation of the proposed changes to the 2015 NSDUH, in particular the sexual orientation questions. It also feels that NSDUH captures critical data, particularly the cigarette brands used. The Campaign for Tobacco-Free Kids, though, recommended that the NSDUH include questions on electronic cigarettes.

NSDUH staff have reviewed all available questions on federal surveys, and have determined that additional development and testing would be needed to ensure that the items be administered properly to different demographic groups, including youth under 18 years of age. SAMHSA is planning to develop and test new e-cigarette questions for future implementation into the NSDUH questionnaire.

The NSDUH tobacco items were reviewed by Laura Kann, who is part of the Youth Risk Behavior Surveillance System (YRBSS) at CDC, on June 30, 2014.

It is HHS policy that ASPE reviews all national surveys. The review for the 2015 NSDUH was conducted in July 2014. The HHS Data Council was kept informed about the status and plans for the 2015 NSDUH.

The Office of National Drug Control Policy (ONDCP) has been consulted and has given input into the 2015 NSDUH redesign. SAMHSA has regular contact with ONDCP regarding the NSDUH and its other data collection systems. Terry Zobeck from ONDCP has provided documentation that SAMHSA has shared the "2015 NSDUH redesign with us and we are supportive of the changes that CBHSQ/SAMHSA are recommending for the survey"

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

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 2003-2014 NSDUHs. The weighted overall response rates for 2001-2013 appear in Table 1. The 2015 NSDUH calls 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 E); Question & Answer Brochure (Attachment F); Tablet Screening Video Script (Attachment G); Appointment Card (Attachment J); Study Description (Attachment K); Introduction and Informed Consent Scripts (Attachment L); Screening Questions (Attachment M); Unable-to-Contact, Controlled Access, and Call-Me Letters (Attachment N); Refusal Letters (Attachment O); and Interview Incentive Receipt (Attachment P).

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%*

*: Number shown is preliminary; final weighted response rate will be updated when available.

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%

Year	Screening	Interview	Overall
2012	86.07%	73.04%	62.87%
2013	83.93%*	71.93%*	60.37%*

*: Numbers shown are preliminary; final weighted response rates will be updated when available.

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 Q) 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 2015 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 L), reading the scripted text aloud to each interview respondent. This statement will appear in the Showcard Booklet (Attachment R) and is read aloud to each interview respondent. As part of the process for obtaining informed consent, respondents are given a Study Description (Attachment K), 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 will read the parental introductory script (Attachment H) 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 S). FIs and Field Supervisors (FSs), who work for a subcontractor to the Contractor, will also complete CIPSEA and project training on ensuring respondent confidentiality and will have signed a notarized Data Collection Agreement (Attachment S) 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.

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 T), 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. 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), updated by SAMHSA on December 26, 2013, would cover the 2015 NSDUH (since this is processed annually).

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

11. Questions of a Sensitive Nature

Many of the NSDUH interview questions concern topics that are 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 L, 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, 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. Questions about sexual orientation and attraction were included in the 2013 DR field test (OMB No. 0930-0334) and are discussed in more detail in section A.1. Several items previously in the CAPI portion of the NSDUH interview, including questions about school and work attendance, were tested in the DR in ACASI to offer increased privacy and will remain in ACASI for 2015.

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 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.

No signed consent forms are used; however, verbal consent is obtained as explained above.

12. Estimates of Annualized Hour Burden

For the 2015 NSDUH, the sample has been designed to yield approximately 67,500 completed interviews. It will be necessary to sample approximately 178,122 households and complete approximately 125,176 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, Hispanicity, and age.

Based on experience with the 2014 screening process and experience gained in 2012 and 2013 with the QFT and DR, administration of the screening questions is expected to take an average of five minutes per SDU.

Initial timing data indicate the NSDUH questionnaire tested in the DR took about 60 minutes to administer, on average. Since there are only a few changes to the 2015 questionnaire from the DR questionnaire, it is estimated that the average amount of time required to administer the 2015 CAI Questionnaire (Attachment U) will also be approximately 60 minutes, including two minutes for the Quality Control Form (Attachment T).

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 2015 NSDUH is 12 months, spanning the period from January through December 2015. The annualized estimated respondent burden for the 2015 NSDUH is shown in Table 3. The hourly wage of \$14.61 was calculated based on weighted data from the 2012 NSDUH and respondents' reported personal annual income.

Table 3. Annualized Estimated Respondent Burden for 2015 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	125,176	1	125,176	0.083	10,390	\$14.61	\$151,798
Interview	67,507	1	67,507	1.000	67,507	\$14.61	\$986,277
Screening Verification	3,755	1	3,755	0.067	252	\$14.61	\$3,682
Interview Verification	10,126	1	10,126	0.067	678	\$14.61	\$9,906
Total	125,176		206,564		78,827		\$1,151,663

13. Estimates of Annualized Cost Burden to Respondents

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

14. Estimates of Annualized Cost to the Government

Total costs associated with the 2015 NSDUH are estimated to be \$59,032,807 over a 48-month contract performance period. Of the total costs, \$53,402,401 are for contract costs (e.g., sampling, data collection, processing, reports), and approximately \$5,630,406 represents CBHSQ costs to manage/administrate the survey. The annualized cost is approximately \$14,758,202. This represents a total increase in costs from the 2014 survey of approximately \$1,991,053. The main reason for the increase in costs is the purchase of new equipment for data collection. For additional information about the new equipment, see section A.3.

15. Changes in Burden

Currently there are 78,317 total burden hours in the 2014 OMB inventory. The 2015 NSDUH is requesting 78,827 burden hours. This program change represents an increase of 510 burden hours. This slight increase is due to a decline in response rates, which results in the need to contact additional dwelling units to yield the targeted number of completed interviews.

16. Time Schedule, Publication and Analysis Plans

Plans for the 2015 survey data involve six major types of data products: (a) two overall reports that present summary results from the 2015 NSDUH (available at the annual HHS press release of NSDUH data or soon thereafter); (b) State findings; (c) analytic reports; (d) Public Use Data File (PUF); (e) Restricted Use Data File (R-DAS); and (f) Data Portal Data File System. Descriptions of major products, as well as approximate delivery dates follow. Table 4 includes a schedule for the 2015 NSDUH.

(a) Overall Reports

National Findings from the 2015 NSDUH (September 2016). This report will present highlights and detailed findings from each data collection year. It consists of a series of exhibits, both graphic and tabular, presenting recent substance use trends by recency of use and numerous demographic characteristics. Essentially, this report examines substance use incidence and prevalence in 2015, trends since 2002, demographic correlates of substance use, substance use patterns, and public perceptions of the harmfulness of illicit substance use as well as opportunities to use drugs. Final weighted and edited data are used to construct the tables.

National Mental Health Findings Report (November 2016). This report will produce detailed mental health findings from the 2015 data collection year. It consists of tables and narrative highlights summarizing prevalence by mental health measures, trend analysis of drug use for selected mental health measures, and socio-demographic tables by mental health measures.

(b) State Findings

State Findings (Early 2017). Data from the combined 2014 and 2015 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 2014-2015 SAEs, significant tests of change between the 2013-2014 and the 2014-2015 SAEs will be included.

(c) 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.

(d) Public Use Data File

Public Use Data File (October 2016). This data file is created from the Master file, and the variables delivered on the Analytic Data File serve as the base for the PUF. Each analytic variable is reviewed for potential disclosure risk, and each one is retained, deleted, or receives further treatment for the PUF. Recoded and logically imputed variables created for the National Findings report produced each year are also included to complete the PUF. The data treatment process has been enhanced over several years to ensure the data remain confidential.

(e) 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 five pair-year data files, 2002-2003, 2004-2005, 2006-2007, 2008-2009 and 2010-2011. Similarly, there are two 4-year files, 2002-2005 and 2006-2009, one 8-year file, 2002-2009 and one 10-year file, 2002-2011 which is under current development. There is no treatment to the variables and the files are delivered to the Substance Abuse and Mental Health Data Archive (SAMHDA) and SAMHSA. A set of variables 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.

(f) 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 their Analytic form, i.e. no additional treatment. In addition to the Base Variables, all other Analytic variables are eligible for agents but they must apply for them, and SAMHSA determines whether they may be added to the agent's data file.

Table 4. Project Schedule for the 2015 NSDUH

Activity	Time Frame
Design and select area frame sample	January 2014 to March 2014
Prepare field Segment Kits	February 2014 to May 2014
Prepare for and conduct field staff training	February 2014 to January 2015
Recruit/train field staff to list SDUs	March 2014 to May 2014
Conduct field listing and subsequent keying of SDUs	April 2014 to January 2015
Program the screening and interview instruments	August 2014 to October 2014
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2014 to January 2015
Conduct screenings and interviews	January 2015 to December 2015
Conduct full-year data processing and file preparation	January 2016 to March 2017
Prepare Trend Tables and Special Tabulations: <ul style="list-style-type: none"> • Finalize Shells • Finalize Annual Tables 	March 2016 June 2016
Prepare Raw Data Files	May 2016
Release Preliminary Weighted Data Files	May 2016
Finalize Sampling Error Report	July 2016
Prepare State Findings	August 2016 to March 2017
Release Final Analytic Data File and documentation	September 2016
Publish National Findings	September 2016
Publish Mental Health Findings	November 2016
Release Public Use Data File	October 2016
Publish Methodological Resource Book	March 2017

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.