

2012/2013 National Survey on Drug Use and Health - Revision

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

NSDUH Main Study

The Substance Abuse and Mental Health Services Administration (SAMHSA), sponsor of the National Survey on Drug Use and Health (NSDUH), submits a revision for approval from the Office of Management and Budget to conduct the 2012 and 2013 NSDUH. The conduct of the NSDUH is paramount in meeting a critical objective of SAMHSA's mission, i.e., to maintain current data on the incidence and prevalence of substance use in the United States. The NSDUH has been conducted on a periodic basis from 1971-1988, and annually since 1990. The 2012 and 2013 surveys will represent the thirty-second and thirty-third in the series (OMB No. 0930-0110).

The 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 United States population.

The NSDUH provides current data on substance use incidence and prevalence for the U.S. population – aged 12 or older – as well as each state. Eight States are designated as large sample States (California, Florida, Illinois, Michigan, New York, Ohio, Pennsylvania, and Texas) with target sample sizes of 3,600. For the remaining 42 States and the District of Columbia, the target sample size was 900. This approach ensures there is sufficient sample in every State to support small area estimation (SAE) while at the same time maintaining efficiency for national estimates.

Information collected through the NSDUH has multiple applications, including: (1) 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) the study of the use of health care resources for treatment of substance abuse and mental health problems; and (5) assisting federal, state and local agencies in the allocation of resources, and the proper design and implementation of substance abuse prevention, treatment, and rehabilitation programs.

The NSDUH instrument is administered by computer-assisted interviewing (CAI) using a laptop computer. The household screening and respondent selection procedures will be administered using a hand-held computer. The length and content of the screening questions and the overall screening process will remain essentially the same in 2012 and 2013 as in 2011.

The sample design for 2012/2013 will be the same as it was for the 2011 CAI sample in that it will be large enough to facilitate the reporting of drug use incidence and prevalence estimates for each of the 50 States, and the District of Columbia. The expansion of the

sample size, which was initiated in 1999, was proposed in the President's FY 1998 budget request, and funded by the Congress, with stipulations described in the Conference Report 105-390, accompanying H.R. 2264, Appropriations for the Departments of Labor, Health and Human Services and Education for Fiscal Year 1998.

Mental Health Surveillance Study

In December 2006, a meeting of expert consultants was convened by SAMHSA's Center for Mental Health Services (CMHS) to solicit recommendations for mental health surveillance data collection strategies. A summary of this meeting is included in Attachment X. The panel recommended conducting methodological studies to calibrate NSDUH mental health and impairment screening tools with a 'gold standard' clinical psychiatric interview to create a statistically sound measure that may be used to estimate the prevalence of serious mental illness (SMI) among adults (age 18+).

Based on these recommendations, a mental health surveillance study (MHSS) was conducted as an embedded split-sample follow-up study within the 2008 NSDUH. Analysis of data from the first 2 quarters of 2008 (approximately 750 adults) determined one impairment scale that, combined with a psychological distress score, best predicted SMI as determined from the clinical interview. This single impairment scale, a modified version of the World Health Organization-Disability Assessment Scale (WHO-DAS) (Rehm et al, 1999), was administered in the 2009-2011 NSDUHs and will also be included in the 2012/2013 NSDUH.

The Mental Health Surveillance Study will be conducted in conjunction with the 2012 and 2013 instruments as well. The modified version of the WHO-DAS will continue to be administered to the entire adult sample. The Structured Clinical Interview for DSM-IV- TR Axis I Disorders Non-patient Edition (SCID-I/NP, 2/2007 revision) (First, M; Spitzer, R; Gibbon, M; & Williams, J; 2002) was tailored for the study and will continue to be used as the follow-up interview. Data from these interviews will be analyzed annually to update the calibration of the screening measure. The procedures for conducting the survey remain the same. Approximately 1,500 clinical follow-up interviews will be completed with adults (18+) each year, with approximately 375 completed per quarter (see Exhibit 1 in Attachment N).

Embedding the MHSS in the regular sample provides an opportunity to recruit respondents for the clinical follow-up without incurring additional screening costs. A sub-sample of respondents will be selected with probabilities based on their K-6 scores. The K-6 score is a measure of psychological distress that ranges from 0 (lowest) to 24 (highest). A score of 13 or higher indicates serious psychological distress. The score is derived from the following six items that refer to one month in the past 12 months when the respondent felt the most depressed, anxious, or emotionally stressed: how often felt nervous (DSNERV1), how often felt hopeless (DSHOPE), how often felt restless (DSFIDG), how often couldn't be cheered up (DSNOCHR), how often felt everything was an effort (DSEFFORT), and how often felt down, no good, or worthless (DSDOWN). The K-6 score will be calculated within the CAI instrument and persons will be sampled using a selection algorithm that ensures an adequate sample size across the range of K-6 scores in order to maximize the power of the analysis.

2. Purpose and Use of Information

The purpose of the survey is to collect current data on substance use incidence and

prevalence and mental health statistics for the total U.S. population as well as each State, and to issue reports on the survey results. The sample is sufficient to support small area estimates 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, the Office of National Drug Control Policy (ONDCP), and other Federal agencies interested in the incidence and prevalence of substance use. The 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, and evaluate the overall impact that Federal and State programs have on drug demand. The NSDUH will provide a useful indicator of individual States' overall success at reducing youth substance use. In conjunction with other data sources, the NSDUH data will provide a means for assessing and improving outcomes of prevention and treatment services. It will help SAMHSA identify areas where serious substance abuse problems exist and provide assistance to States to help them develop and adopt targeted responses for those problems. Also, many special requests for survey information emanate from the White House, Congress, and various State and local government agencies. The questionnaire asks for the minimum information necessary to meet the needs of Federal policy makers and the substance abuse research, prevention, and treatment communities.

The Department of Health and Human Services (DHHS) continues to affirm the need for annual NSDUH surveys as essential to the President's annual Drug Control Strategy and Federal objectives related to substance use. Since the NSDUH is the nation's only 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 will 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. Data from the NSDUH are also used for measurement of program performance and improvement including Quality Outcome Measures, GRPA and other requirements.

Because mental health issues are correlates of substance abuse, SAMHSA continues to include questions on mental health and utilization of mental health services in the 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 U.S. SAMHSA will use data from the mental health surveillance study described in item A.1 above to estimate the prevalence of SMI among adults.

To look specifically at depression, the 2004 NSDUH introduced two depression modules – one for adults and one for youths. The data collected focuses 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 2005-2011 NSDUHs, and will be included in the 2012/2013 instrument as well. A detailed discussion of the 2012/2013 questionnaire is presented in section B.2.

3. Use of Information Technology

The NSDUH study has been administered via computer-assisted interviewing (CAI) since 1999. The interview is administered using audio computer-assisted self-interviewing (ACASI) for the more sensitive questions, representing most of the interview; the remainder of the interview is administered using computer-assisted personal interviewing (CAPI).

The CAPI/ACASI technology affords a number of advantages in the collection of survey data. First, this methodology permits the instrument designer to incorporate more complex routings into the questionnaire compared to a paper-and-pencil instrument. The computer can be programmed to implement complex skip patterns and fill specific wordings based on answers previously provided by the respondent. Errors made by interviewers (and respondents) due to faulty implementation of skip instructions are virtually eliminated. A second feature relates to the consistency of data. The computer can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This 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. Also, the ACASI technology permits nonreaders to complete the interview in total privacy.

CAPI/ACASI technology permits greater expediency with respect to data processing and analysis, e.g. a number of back-end processing steps, including editing, coding, and data entry become part of the data collection process. Data are transmitted via modem 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.

There is evidence that the ACASI methodology is especially useful for surveys of sensitive topics. Providing the respondent with a methodology that improves privacy and confidentiality makes reporting of potentially embarrassing, stigmatizing, and illegal behaviors (e.g., drug use, mental health issues) less threatening and enhances response validity and response rates.

The NSDUH will continue to use iPAQ hand-held computers to conduct household screening interviews. The primary advantage of this computer-assisted methodology is improved accuracy in selecting the correct household member for an interview. The computer automatically selects the correct household member based on the demographic variables entered, thus substantially reducing the probability for human error.

The selection of interview respondents for the clinical follow-up interview will be pre-programmed into the CAI instrument and will be based on the respondent's K-6 score. For those selected follow-up interview respondents, follow-up interview recruitment scripts that are programmed within the NSDUH main study questionnaire will be administered at the end of the initial interview using computer-assisted personal interviewing (CAPI). The field interviewer will not know if the respondent is selected for the follow-up interview until the recruiting scripts appear at the end of the CAI program. Contact information for those who agree to participate will be entered in the laptop. This information will be posted to a secure website for access by the clinician assigned to contact the respondent for the follow-up interview. The follow-up SCID interview will be administered via telephone on a paper and

pencil (PAPI) SCID instrument.

4. Efforts to Identify Duplication

The NSDUH is the only survey of substance use in the United States with a sample size capable of producing high quality national and separate state incidence and prevalence estimates, especially by detailed demographic variables. No other survey provides the level of detail on substance use and abuse as provided by the NSDUH. No duplication of effort has been identified.

Several other surveys and data systems collect data on substance use, abuse, and dependence. However, it is important to understand the methodological differences between the different surveys and the impact that these differences could have on estimates of substance use prevalence.

The Monitoring the Future (MTF) study is a national survey, sponsored by the National Institute on Drug Abuse (NIDA) that tracks substance use trends and related attitudes among America's adolescents. 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. Since the NSDUH is an annual survey of the civilian, noninstitutionalized population of the United States aged 12 years old or older, the two studies clearly 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 et al., 1997).

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). The MTF conducts self-administered surveys in a school setting and by mail. The NSDUH is conducted in the household using a computer-assisted instrument. When the NSDUH is subset to the same student population covered by the MTF, comparisons between the MTF and NSDUH estimates generally have shown NSDUH substance use prevalence levels to be lower than MTF estimates, with differences tending to be more pronounced for 8th graders. The lower prevalences in the NSDUH may be due to more underreporting in the household setting as compared with the MTF school setting.

The Youth Risk Behavior Survey (YRBS) is a component of the Centers for Disease Control and Prevention's (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 (STDs); (e) unhealthy dietary behaviors; and (f) physical inactivity. The YRBSS 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 only includes 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 the NSDUH. As a result, the prevalence estimates of illicit drug use are generally much higher from the YRBS.

In 2000, a series of papers comparing different aspects of the NHSDA, MTF, and the YRBS was commissioned by the U.S. Department of Health and Human Services (DHHS). Under

contract with the Office of the Assistant Secretary for Planning and Evaluation, Westat, Inc., identified and funded several experts in survey methods to prepare these papers. The papers were published in the *Journal of Drug Issues* (Hennessy & Ginsberg, 2001). The major findings of this study indicate that differences in survey methodology may affect comparisons of prevalence estimates among youths. The study also found that all three surveys were well designed and managed, but they each have different purposes.

The Behavioral Risk Factor Surveillance System (BRFSS) is an annual, State-based telephone survey of the civilian, noninstitutionalized adult population aged 18 or older and is sponsored by the Centers for Disease Control and Prevention (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 audio computer-assisted self-interviewing (ACASI) in NSDUH, which is considered to be more anonymous and yields higher reporting of sensitive behaviors, was offered as an explanation for the lower rates in BRFSS (Miller et al., 2004).

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 comprehensive assessments of drug use, abuse, and dependence, as well as associated mental disorders. While the NSDUH is an annual survey of the civilian, noninstitutionalized population of the United States aged 12 years old 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). The NESARC is designed to be a longitudinal survey, whereas the NSDUH provides annual cross-sectional data. Another methodological difference is that sensitive questions in the NSDUH are self-administered while the NESARC is wholly interviewer-administered. Methodological variables, 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 (Gruzca et al., 2007).

The Center for Behavioral Health Statistics and Quality (CBHSQ), formerly the Office of Applied Studies, SAMHSA, is in contact with all major federal health survey managers and is aware of no other efforts to calibrate mental health screening and impairment scales to a structured clinical interview to derive national estimates of Serious Mental Illness. Mental health assessment experts convened in December 2006 and recommended a study such as the NSDUH Mental Health Surveillance Study to address a prominent data gap; thus, there is no evidence of duplication of effort.

5. Involvement of Small Entities

This survey does not involve small businesses or other such entities.

6. Consequences If Information Collected Less Frequently

The existence of substance abuse patterns and behaviors is a rapidly evolving and changing phenomenon, which 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 published on April 7, 2011 (Vol. 76, page 19380) solicited no comments on the 2012/2013 NSDUH.

It is DHHS policy that all national surveys are reviewed by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The review for the 2011 survey was conducted in May 2011. ASPE commented that the supporting statement needed to clarify the youth informed consent procedures. This clarification has been made. The DHHS Data Council has been kept informed about the status and plans for the 2012/2013 NSDUH.

Appendix A of the 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

On October 18, 2001, the use of a \$30.00 incentive was approved by OMB for use in the 2002 NSDUH survey. The 2002 NSDUH experienced an increase in the weighted overall response rate (screening * interviewing) from 67% to 71%. Prior OMB approval was provided for the continued use of the \$30.00 incentive for the 2003-2011 NSDUH surveys. The weighted overall response rates for 2003-2010 appear in the table below. The 2012/2013 NSDUH calls for the same incentive plan, whereby a \$30.00 incentive payment will be given to respondents upon completion of the interview. The incentive payment is mentioned in the following respondent materials: Lead Letter (Attachment D), Appointment Card (Attachment F), Study Description (Attachment G), Introduction and Informed Consents (Attachment L), Screening Questions (Attachments H), Question and Answer Brochure (Attachment I), Unable to Contact Letters (Attachment Q), Call-Me Letters (Attachment R), Refusal Letters (Attachment S) and Interview Payment Receipt (Attachment O).

| Year | Overall Response Rate % |
|-------------|------------------------------------|
| 2001 | 67 |
| 2002 | 71 |
| 2003 | 71 |
| 2004 | 70 |
| 2005 | 70 |
| 2006 | 68 |
| 2007 | 67 |
| 2008 | 67 |
| 2009 | 67 |
| 2010 | 66 |

The telephone interview to be completed for the MHSS will constitute an additional burden on respondents, and may make it more difficult to obtain respondent participation. To maintain adequate response rates, SAMHSA believes it is necessary to offer respondents an additional \$30 payment for completing the follow-up clinical interview. The clinical interview will take about the same amount of time as the initial interview, so an equitable incentive is necessary. Research studies have shown that providing incentives before the interview increases the likelihood that participants will complete the interview (Groves & Couper, 1998). Therefore, SAMHSA believes it is necessary to provide the additional \$30 follow-up incentive at the end of the NSDUH main interview, once the participant agrees to the follow-up interview. Prior OMB approval was provided for the use of the \$30.00 incentive in the 2008-2011 MHSS. Respondents who agree to complete the follow-up interview will receive a total of \$60 at the end of the initial interview. The cash payment for the follow-up interview is mentioned in the following respondent materials: Follow-up Interview Recruitment Scripts (Attachment B, pages 442-443), Follow-up Study Description (Attachment T), and Follow-up Interview Payment Receipt (Attachment W).

10. Assurance of Confidentiality

Concern for the confidentiality and protection of respondents' rights has always played a central part in the implementation of the National Survey on Drug Use and Health and will continue to be given the utmost emphasis.

Interviewers are thoroughly educated in methods for maximizing a respondent's understanding of the government's commitment to confidentiality. Furthermore, interviewers 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. (Attachment A: notice of approval of Federal-Wide Assurance, submitted by RTI to the Office for Human Research Protections (OHRP), DHHS in compliance with the requirements for the protection of human subjects (45 CFR 46)).

The interview incorporates several procedures to ensure that respondents' rights will be protected. The interviewer introduces himself/herself and the session with a consent statement. This statement will appear in the Showcard Booklet (Attachment L) and will be read out loud 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 (included as Title V in the E-Government Act of 2002, P.L. 107-347) and the protection that it affords. Specifically, the Study Description states that respondents' answers will only be used by authorized personnel for statistical purposes and cannot be used for any other purpose.

The questionnaire uses techniques to afford privacy for the respondent during the interview process. The audio computer-assisted self-interviewing (ACASI) portion of the instrument will maximize 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, then key his or her own responses into the computer via the keyboard.

Hard copy materials generated during the course of the interview are marked for identification by the interviewer according to specific instructions. Name, address, or other easily traceable marks are never noted on the hard copy materials, except on the Quality Control Form (Attachment C) at the end of the interview (with the respondent's permission); even then, the name is not recorded for interview respondents. Furthermore, the respondent places the Quality Control Form in an envelope and seals it after recording the information. The respondent is told of these procedures in advance. The Quality Control Form is mailed directly to the Contractor's main office in North Carolina.

With the CAI methodology, all sensitive data are entered privately by the respondent, and completed interview data are electronically transmitted to the Contractor's offices on a regular basis via secure encrypted data transmission. Interviewers are unable to review or to edit questionnaire data as the completed interview files are locked. Also, once the respondent has completed the ACASI portion of the interview, the ACASI section is locked, so that the interviewer is unable to back up into this area and review the respondent's most sensitive data. On the data file, respondents are identified only by a link number assigned to screening files and questionnaires/interviews. Although the link number is associated with a location number and a dwelling unit number, this location information is deleted by the Contractor before the delivery of data to SAMHSA. 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 any means of identifying addresses of sample dwelling units. The permanent sampling records show only the general location in which interviews were conducted; there is no record of specific dwelling units contacted.

The MHSS will incorporate several procedures to ensure that respondents' rights will be protected, including procedures developed for the main NSDUH. The interviewer will introduce the follow-up interview with recruitment scripts (Attachment B, pages 442-443). These scripts will appear on the computer screen at the end of the initial CAI interview and will be read out loud to each interview respondent selected for the MHSS. As part of the process for obtaining informed consent for the follow-up interview, respondents will be given a Follow-up Study Description (Attachment T), which includes information on the Confidential Information Protection and Statistical Efficiency Act of 2002 (included as Title V in the E-Government Act of 2002, P.L. 107-347) and the protection that it affords.

Specifically, the Follow-up Study Description states that respondents' answers will only be used by authorized personnel for statistical purposes and cannot be used for any other purpose. The dwelling unit address information, which is maintained in a separate file for Contractor use in sampling, fielding, and weighting cases, as well as the respondent's first name, and phone number will be destroyed when all final data files are delivered to SAMHSA and approval received by the SAMHSA Project Officer.

Although the respondent's first name and phone number will be collected within the main interview, it will be used only for re-contact purposes. Once the CAI data are transmitted and arrive at RTI, the respondent's name, phone number, and text regarding the best time to call will be split off into a separate database with only the random number ID for linkage. The rest of the CAI data will be converted into a SAS data file format and merged onto the master data file.

The follow-up interview will be conducted over the telephone by clinicians trained in the administration of the SCID. All clinical interviewers will receive training on the importance of keeping all information learned from respondents confidential. A confidentiality pledge will be read and signed by all clinical interviewers during the project training process (See Attachment Y).

Follow-up interview materials are marked for identification by the interviewer using a randomly-generated 7-digit number called the QuestID. The respondent's address or other easily traceable marks will not be included on the SCID paper form.

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

There will be no Privacy Act System of Records established for this effort.

11. Questions of a Sensitive Nature

As mentioned in section A.1 above, SAMHSA is required to report annually on the incidence and prevalence of substance abuse and mental health problems due to Section 505 of the Public Health Service Act. Many safeguards, including the mode of questionnaire administration, have been incorporated into the NSDUH study design in order to improve the collection of data on sensitive issues/information. As a part of the interview process and upon introduction, the interviewer informs the respondent why the information is necessary, indicates who sponsors the Survey, requests consent to conduct an interview, and explains the procedures which assure confidentiality. For respondents between the ages of 12 and 17, verbal consent is obtained from both the parent and the youth. (See Attachment L, Showcard Booklet, for verbal consent text.) However, every attempt is made to ensure that the actual interview is conducted without parental observation or intervention.

Answers to sensitive questions, including all substance use questions and mental health questions, are obtained by closed interview design. In the ACASI administration, the respondent enters his/her answers directly into the computer. The interviewer does not see the answers. Data from the electronic interviews are transmitted regularly to the Contractor via secured data transmission. All CAI data are telecommunicated to the Contractor's office, and are identified with a respondent number, which is a code associated with the sample dwelling unit. There is no system of records which identifies respondents. The questionnaire data are processed immediately upon receipt at the Contractor's facilities and

all links between a questionnaire and the respondent's address are destroyed after all data processing activities are completed.

No signed consent forms are used; however, verbal consent is obtained as explained above. The listing of selected dwelling unit locations and addresses are kept under locked and secured conditions and destroyed after all data processing activities are completed.

The follow-up interview will be delivered by mental health clinicians trained in administering the SCID and deriving DSM-IV diagnoses from structured clinical interviews. The clinician will administer the SCID over the telephone from a private location in his/her home or office. When calling to conduct the SCID, the clinician will ask the respondent to go to a private location for the duration of the interview. The clinician will explain to the respondent that the only identifying information he/she has is the respondent's first name and telephone number and that this identifying information will be discarded after data collection ends. The clinician will repeat the confidentiality assurances and will ask for permission to record the interview (Attachment U) for quality control purposes. Permission to record the interview is not a requirement to complete the interview. The clinician will note the respondent's answers on a paper SCID response sheet and will keep the questionnaire in a secure location until shipping them via Federal Express to RTI for a quality control (QC) review by specially-trained clinical supervisors. After this QC step, the paper SCIDs will be technically edited and keyed. All paper SCIDs and audio recordings will be destroyed approximately six months after the end of data collection.

All clinical interviewers will be issued project-owned laptop computers, preconfigured with the following software.

- Pointsec whole-disk encryption software
- Custom software to electronically capture audio recordings of clinical interviews
- Custom software to automate upload of audio files

All clinical interviews for which the respondent grants permission will be recorded using a laptop computer that is connected between the clinical interviewer's phone and wall phone jack using a telephone line splitter. The audio recording of clinical interviews will proceed according to the following sequence, in which the clinical interviewer:

1. Connects their telephone to their project-owned laptop using a line splitter
2. Tests their laptop-phone connection by placing a test call
3. Initiates a telephone call to the respondent and obtains informed consent
4. Uses laptop software to begin recording the clinical interview
5. Completes the clinical interview and stops recording
6. Uses custom laptop computer software to securely upload the audio file to RTI

The above protocol provides a high degree of protection for the confidentiality of the audio files. Audio files are encrypted both at rest and also during transmission. The Pointsec whole-disk encryption software protects the audio files while they reside on the clinical interviewers' laptops. To move interview files from laptops back to servers at RTI, custom software on the laptop will use secure FTP and/or HTTPS protocols to make sure the entire file transfer is securely encrypted for transfer over the public Internet. Once files are received at RTI, they will be protected by the complete set of security controls that protect RTI's corporate computer networks.

Subsequent to the transfer of audio files to RTI, authorized project researchers and management staff will use a secure web-based file sharing facility to either download or directly listen to the audio recordings. Again, any transfer (even in-place playback) of the recordings will be strongly encrypted during transport across the public Internet using the HTTPS protocol. The project-owned laptops used by the above mentioned authorized project staff will be preconfigured with PointSec disk encryption software to insure full data protection.

In summary, at any point in time, an audio file may potentially reside in only three places:

- On the encrypted hard drive of the clinical interviewer who performed the interview
- On an RTI file server, protected from the public internet by our corporate IT security controls
- On the encrypted hard drive of a project-owned laptop issued to a properly authorized person for use solely on this study.

All audio recordings will be erased (from RTI file servers and project-owned laptops) by June 30 of the year following data collection.

12. Estimates of Annualized Hour Burden

The total sample size for the 2012/2013 National Survey is approximately 67,500 persons per year. This sample size is required to ensure reliable state-level estimates for each of the 50 states, as well as estimates on the many sub-populations included in NSDUH specifications, e.g., Blacks, Hispanics, youth, etc. It is necessary to screen approximately 191,100 households to obtain the requisite survey sample size.

The experience with the first half of 2011 indicated that the average interview time remained approximately 60 minutes.

Based on the questionnaire having the same length, it is estimated that the average amount of time required to administer the 2012/2013 CAI questionnaire will also be approximately 60 minutes, including 2 minutes for the Quality Control Form. Administration of the screening questions will take an average of 5 minutes per dwelling unit. Based on the 2012/2013 clinical interview having roughly the same length as the 2011 clinical interview, the follow-up clinical interview is estimated to take on average an additional 60 minutes.

Screening verification and interview verification contacts both take an average of 4 minutes and are administered only to a subsample of the cases. An approximate fifteen percent random sample of each interviewer's work (i.e., completed interviews) will be verified. In addition to the verification of completed interviews, certain completed screening codes (vacant, not primary residence, not a dwelling unit, DU contains ONLY military personnel, respondents living at residence for less than half of the quarter, and no one selected for interview) will be verified. Previous experience indicates that approximately 60% of all screenings will result in one of these six screening codes. An approximate five percent random sample of all such screening codes will be selected for verification follow up.

The hourly wage of \$14.71 was calculated based on weighted data from the 2009 NSDUH respondents' personal annual income.

The data collection field period for the 2012/2013 NSDUH is 12 months long, spanning the period from January through December of each survey year. The respondent burden for the 2012/2013 NSDUH is shown in the following table:

Annualized Estimated Burden for 2012/2013 NSDUH

| <i>Instrument</i> | <i>No. of Respondents</i> | <i>Responses per respondent</i> | <i>Hours per response</i> | <i>Total burden hours</i> | <i>Hourly Wage rate</i> | <i>Annualized costs</i> |
|----------------------------------|---------------------------|---------------------------------|---------------------------|---------------------------|-------------------------|-------------------------|
| Household Screening | 191,100 | 1 | 0.083 | 15,861 | \$14.71 | \$233,315 |
| Interview | 67,500 | 1 | 1.000 | 67,500 | \$14.71 | \$992,925 |
| Clinical Follow-up Certification | 90 | 1 | 1.000 | 90 | \$14.71 | \$1,324 |
| Clinical Follow-up Interview | 1,500 | 1 | 1.000 | 1,500 | \$14.71 | \$22,065 |
| Screening Verification | 5,400 | 1 | 0.067 | 362 | \$14.71 | \$5,325 |
| Interview Verification | 10,125 | 1 | 0.067 | 678 | \$14.71 | \$9,973 |
| TOTAL: | 191,190 | | | 85,991 | | \$1,264,927 |

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 2012/2013 National Survey on Drug Use and Health are estimated to be \$107,665,364 over a 56-month contract performance period. Of the total costs, \$101,859,109 are for contract costs, e.g., sampling, data collection, processing, reports, etc., and approximately \$5,806,255 represents SAMHSA costs to manage/administrate the survey. The annualized cost is approximately \$23,071,149.

Total costs associated with the MHSS are estimated to be \$2,843,832 over a 56-month performance period. Of the total costs, \$2,499,436 is for contract costs, e.g., sampling, data collection, processing, reports, etc., and approximately \$344,396 represents SAMHSA costs to manage/administrate the survey. The annualized cost is approximately \$609,393.

The total annualized cost is 23,680,542.

15. Changes in Burden

Currently there are 88,489 total burden hours in the 2011 OMB inventory. The 2012/2013 NSDUH is requesting 85,991 total burden hours per year. The decrease is due to the special Gulf Coast oversample of 2000 cases that was conducted in 2011 only. With the oversample, an estimated 196,720 households were required to be screened to achieve the target sample size in 2011. With the reduction of an estimated 2000 cases in 2012/2013, only 191,100 households screenings will be needed, resulting in an overall reduction in burden of 2,497 hours.

Estimated Burden Reduction for 2012/2013 NSDUH

| | <i>2011 No. of Respondents</i> | <i>2012/13 No. of Respondents</i> | <i>Difference</i> | <i>Hours/response</i> | <i>Total Burden Reduction</i> |
|------------------------|--|---|-------------------|-----------------------|-----------------------------------|
| Household Screening | 196,720 | 191,100 | 5,620 | .083 | 466 |
| Interview | 69,500 | 67,500 | 2000 | 1.0 | 2000 |
| Screening Verification | 5,560 | 5,400 | 160 | .067 | 11 |
| Interview Verification | 10,425 | 10,125 | 300 | .067 | 20 |
| TOTAL: | | | 8,080 | | 2,497 |

16. Time Schedule, Publication and Analysis Plans

Plans for the 2012/2013 Survey data involve four major types of products: an early report that presents results from the 2011 NSDUH (available at the annual DHHS press release of NSDUH data); two state specific reports; five analytic reports; and a public use data file. Descriptions of major publications, as well as delivery dates for major publications, follow.

NATIONAL FINDINGS FROM THE 2012/2013 NSDUH (September, 2013 and 2014) - These reports will present highlights and detailed findings from each data collection year. It consists of a series of exhibits, both graphic and tabular, presenting recent trends of substance use by recency of use and numerous demographic characteristics. Essentially, this report examines substance use incidence and prevalence in 2012/2013, 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.

STATE FINDINGS REPORT (Early, 2015) - A state data report (approximately 200 pages) will present substance use incidence and prevalence estimates for each of the 50 states and

the District of Columbia. It will also document the methodology in detail.

NATIONAL MENTAL HEALTH FINDINGS REPORT (November, 2013) – This report will produce detailed mental health findings from the 2012 data collection year. It consists of tables and narrative highlights summarizing prevalence by mental health measure, trend analysis of drug use for selected mental health measures, and socio-demographic tables by mental health measures. It will include a calibration study for estimation of mental illness using combined MHSS and EMHSS data.

ANALYTIC REPORTS - Additional data analyses and special analytical papers will be produced and released as part of the SAMHSA, CBHSQ Analytic Series or A report series. Reports of findings from the MHSS will also be produced. 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.

2012 NSDUH PROJECT SCHEDULE

| <u>ACTIVITY</u> | <u>TIME FRAME</u> |
|--|-------------------------------|
| Design and select area frame sample | December 2010 to March 2011 |
| Prepare field Segment Kits | January 2011 to May 2011 |
| Recruit/train field staff to list Sample Dwelling Units (SDUs) | March 2011 to May 2011 |
| Field listing and subsequent keying of SDUs | April 2011 to January 2012 |
| Recruit remaining field staff and generate all required materials/assignments for distribution | August 2011 to January 2012 |
| Finalize programming of NSDUH interview | August 2011 to October 2011 |
| Prepare for and conduct field staff training | May 2011 to January 2012 |
| Conduct NSDUH interviews | January 2012 to December 2012 |
| Data processing and file preparation | January 2013 to March 2014 |
| Trend Tables and Special Tabulations: | |
| -- Shells | March 2013 |
| -- Annual Tables | June 2013 |
| Raw Data Files | May 2013 |
| Preliminary Weighted Data Files | May 2013 |
| Final analytic data file and documentation | September 2013 |
| Sampling Error Report | July 2013 |
| National Findings | September 2013 |
| State Small Area Estimation Analytical Report | August 2013 to March 2014 |
| Public Use Data File | December 2013 |
| Methodological Resource Book | March 2014 |

17. Display of Expiration Date

The OMB expiration date will be displayed on all data collection instruments.

18. Exceptions to Certification Statement

The certifications are included in this submission.