National Survey on Drug Use and Health
Questionnaire Field Test
2013 Dress Rehearsal

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

Overview

The National Survey on Drug Use and Health (NSDUH), sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA), is a national survey of the U.S. civilian, non-institutionalized population aged 12 and older. The conduct of the NSDUH (OMB No. 0930-0110) is paramount in meeting a critical objective of SAMHSA's mission to maintain current data on the prevalence of substance use in the United States.

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.

In order to continue producing current data, SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) must periodically update the NSDUH to reflect changing substance use and mental health issues. CBHSQ plans to redesign the NSDUH for the 2015 survey year to achieve two main 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.

A Questionnaire Field Test (QFT) (OMB No. 0930-0334) was conducted in 2012 to test revisions to the questionnaire and other processes associated with these redesign goals. SAMHSA is requesting approval of this revised package to further refine and test the QFT questionnaire and procedures prior to the 2015 redesign by conducting a follow-up Dress Rehearsal (DR) in September and October of 2013.

Questionnaire Field Test Summary

The QFT tested revisions to the NSDUH questionnaire, procedures, and respondent materials associated with the 2015 redesign goals. Data collection was conducted for the QFT during September and October of 2012, with a total of 2,044 interviews completed. Respondents were

selected from a sample designed to represent the civilian, noninstitutionalized population aged 12 years old and older within the 48 contiguous U.S. states and the District of Columbia who indicated they were able to complete the interview in English.

The QFT tested FI and respondent reactions to two revised materials that describe the survey to respondents. These revised materials were the NSDUH Lead Letter mailed to respondents prior to being contacted by an FI and a Question & Answer Brochure that FIs provide to respondents.

In addition to the changes to contact materials, the QFT questionnaire was revised from the 2012 NSDUH questionnaire to improve questions that cause known or suspected problems with data while also including new content to address current data needs. Revisions designed to reduce errors associated with usability problems in the design and layout of the computer-assisted interviewing (CAI) questionnaire were also implemented.

The QFT questionnaire changes included revised front-end demographic questions; a new methamphetamine module; revised questionnaire modules on prescription drugs, special drugs, consumption of alcohol, and health; and revised back-end demographics questions. To aid respondent recall, the QFT questionnaire displayed pill images 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 used for the 2012 NSDUH questionnaire administration. Further, the structure of the questionnaire was revised to group questions about various substances in a more intuitive manner. For example, various questions about methamphetamines from several NSDUH modules were moved to the new methamphetamine module, and questions about several stimulants previously located in the special drugs modules were moved to the prescription stimulants module. Additional detail on questionnaire changes is provided below.

Special attention was paid to redesigning modules that measure prescription drug misuse. This redesign was prompted by challenges and issues associated with measurement of the concept of nonmedical use, which were discussed in a recent NSDUH report on prescription drugs (Colliver, Kroutil, Dai, & Gfroerer, 2006)[1]. 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 et al., 2006)[2]. Also, to address data needs of the U.S. Food and Drug Administration (FDA) and the Office of National Drug

[1] Colliver, J.D., Kroutil, L.A., Dai, L., & Gfroerer, J.C. (2006). Misuse of Prescription Drugs: Data from the 2002, 2003, and 2004 National Surveys on Drug use and Health (DHHS Publication No. SMA 06-4192, Analytic Series A-28.) Rockville, MD; Substance Abuse and Mental Health Services Administration, Office of Applied Studies.

[2] Huang, B., Dawson, D.A., Stinson, F.S., et al. (2006). Prevalence, Correlates and Comorbidity of Nonmedical Prescription Drug Use and Drug Use Disorders in the United States: Results of the National Epidemiological Survey on Alcohol and Related Conditions. *Journal of Clinical Psychiatry,* 67:1062-1073.

Control Policy (ONDCP), questions about drugs that are newly available on the market were added, questions about drugs that are no longer commercially available were deleted, and questions about medical use were added.

In response to Department of Health and Human Services (HHS) data standards, questions on disability status and primary language were added. Also added were questions related to areas of interest that were identified during consultations within and outside the agency, including new questions about military families and an edited definition of binge drinking for females.

To allow for greater respondent privacy as well as shorter administration times, many of the questions in the back-end demographics module became self-administered. To help ensure respondent understanding of computer use, a new tutorial module was included that introduced proxy respondents to the CAI instrument to help them answer the new self-administered proxy questions about respondent and household income and health insurance.

Finally, a modified question about landline telephones and a new question about cell phones in the home were added to the questionnaire.

In addition to the material and questionnaire changes, QFT field interviewers (FIs) tested the use of a new 7-inch touch screen Android tablet computer for screening, interview respondent selection, and case management. On this tablet, FIs completed new FI observation questions about the respondent materials and interview so the questions could be completed thoughtfully and promptly after leaving the respondent's home.

Dress Rehearsal Summary

Using the QFT questionnaire and procedures as the foundation, the DR will further refine and improve the redesigned questionnaire, materials and processes prior to any full scale changes for the 2015 redesigned NSDUH. Key differences between the QFT and the DR include the addition of Spanish interviews and a test of new equipment.

The materials fielded during the QFT will be largely unchanged for the DR, while the questionnaire has been changed slightly. Questionnaire changes include: (a) the addition of two sexual orientation questions to be asked of adults; (b) routine updates to routing and logic; (c) minor changes to question wording throughout the instrument to clarify intent; and (d) the deletion of a question in the Back-end Demographics module about the number of employees who work at the respondent's business. Details of these changes follow.

To meet the Secretary's goal to include "sexual orientation" questions in the 2015 NSDUH, two questions measuring sexual identity and attraction for adults have been added to the ACASI section of the interview. These questions closely resemble those fielded in the National Survey of Family Growth (NSFG) and the National Health and Nutrition Examination Survey (NHANES) both in wording and structure.

The new questions on sexual orientation are also pertinent to Healthy People 2020 Objectives. The need for data and research to document, understand, and address factors that contribute to health disparities in the LGBT community was described in the original LGBT companion document to

Healthy People 2010, documenting the need for the collection of sexual orientation and gender identity in federal, State, and local surveys that routinely collect population-based information on health or social issues. It was noted that sexual orientation and gender identity questions are not asked on most national or State surveys, making it difficult to estimate the number of LGBT individuals and their health needs, while the growing research indicates that LGBT individuals face health disparities.

The inclusion of questions on sexual orientation and sexual identity directly address 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.

Several routing changes within the questionnaire have been implemented to improve the flow of questions. One such routing change took place in each of the four prescription drug modules. In the redesigned prescription drug modules, respondents are asked about initiation of misuse only for those specific prescription drugs that they misused in the past 12 months. SAMHSA uses initiation data in NSDUH to identify persons who were recent (i.e., past year) initiates. However, the QFT questionnaire did not capture information about any additional prescription drugs that last were misused more than 12 months ago. By definition, NSDUH does not consider persons who began misusing prescription drugs more than 12 months ago to be recent (i.e., past year) initiates. In response to this issue, the following routing change has been made: Respondents who report only past year initiation for at least one prescription drug in a given category will be routed to a question that asks whether they misused any drugs in that category more than 12 months prior to the interview date. This change will improve the identification of recent initiates of misuse by screening out additional persons who initiated misuse more than 12 months ago.

Finally, one QFT question about the number of employees in the workplace will be removed for the DR since it is not needed for analytical purposes.

Adding the capability to complete DR interviews in Spanish (since the QFT was not conducted in Spanish) requires an updated Spanish questionnaire and screening program, as well as Spanish translations of respondent materials. In response, the materials and questionnaires needed for the DR have been translated from English to Spanish.

Equipment testing during the DR will focus on a new light-weight laptop to be used to conduct interviews in both English and Spanish. FIs will continue to use the tablet computer from the QFT for screening, respondent selection, and case management, with a few administrative enhancements for the DR.

Conducting data collection for the DR during September and October of 2013 will provide sufficient time to collect, process, and evaluate the findings and then prepare properly for the full-scale NSDUH redesign planned for implementation in January 2015.

2. Purpose and Use of Information

As explained in section A.1, the main goals of the 2015 NSDUH redesign are to: 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. The QFT conducted in late 2012 tested revisions to the questionnaire and processes related to these goals, while the DR will constitute a final test of the questionnaire, methodology, and materials, including an assessment of the new laptop and the Spanish language interview.

The screening and interview data from the QFT are being analyzed to evaluate the total effect on NSDUH estimates from all changes to the protocol for the 2015 redesign. Since the sample size for the QFT was not large enough to quantitatively assess the impact of each change to the NSDUH main study, the statistical focus of the QFT was to measure the apparent impact of the collective set of protocol changes on key NSDUH estimates, overall and by three major age groups. Data from the DR can be used to confirm the QFT results and to further test the changes by comparing DR data to main study data.

The DR will involve screening approximately 3,673 households and conducting 2,000 interviews with selected respondents in September and October of 2013. The DR screening and interviewing data will be compared with both the 2012 NSDUH data and the third and Quarter 4 2013 NSDUH data to assess the impact of the proposed questionnaire and protocol changes. Analysis performed on the QFT data will be continued as necessary for the DR. For instance, other substantive data will also be compared, such as item nonresponse rates, levels of inconsistencies between like items, and rates of drug use, to assess the level of editing and imputation that will be needed with the new questionnaire and to assess the quality of prevalence estimates. Testing and assessment of the redesigned NSDUH questionnaire and procedures must be completed with adequate time for analyzing the results and making final decisions on changes to be made for the redesigned survey for 2015.

3. Use of Information Technology

Data for the DR will be collected in a face-to-face interview setting in respondents' homes using laptop computers, the same method used on the main study. The DR interviews will be administered using ACASI for the more 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).

The NSDUH interview has been administered in this manner since 1999, while continually enhancing and expanding the interviewing program to take advantage of improvements in technology. The CAPI/ACASI methodology permits complex routings and specific, detailed wording fills based on answers previously provided by the respondent. The computerized questionnaire can identify inconsistent responses and attempt to resolve them through respondent prompts, which not only saves processing time but increases data quality as inconsistencies can usually be resolved during the interview. Also, the ACASI technology permits nonreaders to complete the interview in total privacy.

The iPAQ hand-held computers used for screening households on the main study have been discontinued by the manufacturer and therefore must be replaced for the 2015 NSDUH redesign. As part of the QFT, CBHSQ decided to evaluate an alternative device, a 7-inch touch screen Android tablet computer. This same device will be used for screening, respondent selection, and case management on the DR.

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.

CBHSQ is currently evaluating two different models of laptop computers for use in the interview, one of which will be selected for the DR. Both are thin, light ultrabook-style laptops. 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, by nature 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 field tests to assess how changes made to the NSDUH questionnaire and data collection protocol might affect reporting on the NSDUH screening and interviewing questions. To date, no duplication of effort has been identified.

5. Involvement of Small Entities

Data collection for the DR will not involve small businesses or other such entities.

6. Consequences if Information Collected Less Frequently

The redesigned NSDUH survey will enter the field in January 2015. In order to meet this deadline, reporting of the DR results needs to take place in January 2014. This project is a one-time collection and will not be repeated.

This data collection is integral to implementing a redesigned NSDUH in 2015. SAMHSA needs to analyze potential changes to important trend data, data quality, and response rates prior to the redesigned NSDUH. Without testing prior to implementation, SAMHSA will not know the potential impacts the resigned NSDUH might have, particularly those that will be only tested in this round, such as the Spanish language instrument.

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

CBHSQ has consulted with other experts within SAMHSA, including staff from the Center for Substance Abuse Treatment (CSAT), who helped compile a list of 51 State agency contact persons for additional consultation. These 51 agency representatives constituted the sample for the NSDUH

State Data Users Survey (OMB No.: 0930-0290). The survey asked about how the states use the data and what additional topics or changes would make the data more useful.

Guidance and information were also requested from other data users in academia and federal agencies, such as the National Center for Health Statistics (NCHS). As a result of these discussions, several questions being tested for addition to the NSDUH interview are based on questions from the National Health Interview Survey (NHIS).

A Federal Register notice published on March 1, 2013 (Vol. 78, page 13882) elicited seven comments on the 2013 NSDUH DR. The comments came from The Trevor Project; The National Center for Transgender Equality; The American Foundation for Suicide Prevention; The Center for American Progress; The Gay, Lesbian & Straight Education Network; The Fenway Institute at Fenway Health; and The Campaign for Tobacco Free Kids. Most of these organizations focused their comments on the addition of the new sexual attraction and identity questions. The first six organizations requested changes that would allow for the collection of additional detail on lesbian, gay, bisexual, and transgender individuals, especially regarding gender identity. All five of the first organizations listed also identified the need for additional sources of data on suicide prevention and bullying for youth.

The initial focus of most of the comments was based on the assumption that NSDUH interviewers code respondents' gender by observation, which is not accurate. The NSDUH has a screening component in which the respondent reports the gender for each household member. This information is available to the interviewer at the start of each interview. Rather than asking respondents again for gender, the interviewer confirms the respondent's gender and enters it into the instrument to assure that the respondent will receive the appropriate questions. In addition, because NSDUH is a face-to-face interview that first gathers demographic and relationship information about each household member, interviewers have many cues that provide context for confirming the gender of the respondent. Because the NSDUH is a 60-minute interview containing many sensitive questions concerning illicit behaviors, every effort must be taken to assure that the interaction between the interviewer and respondent remains comfortable and pleasant to minimize the risk of potential refusals or break-offs. It can be readily demonstrated that asking someone's gender when face-to-face can be interpreted as offensive. Even so, if there is any ambiguity, NSDUH interviewers are still required to ask the gender of the respondent.

Although SAMHSA recognizes the need for data to better understand the factors that contribute to health disparities in the LGBT community, the NSDUH methodology has its limitations. The NSDUH is designed to provide current data on the use of illicit drugs, alcohol, tobacco, and health-related conditions in the entire U.S. population – aged 12 or older – as well as in each state. In an effort to preserve response rates and control respondent burden, SAMHSA strives to maintain an average interview length of 60 minutes. Therefore, each topic is carefully considered and assessed for whether valid and reliable national estimates can eventually be produced from the questions. Several of the recommendations from the organizations that provided comments centered specifically on gender identity and gathering additional data for the further study of the transgender population. Given the relative size of the transgender population to the sample size of the NSDUH, it is likely that reliable national estimates for this population could not be produced. However, SAMHSA is considering ways to possibly do this in the future.

SAMHSA agrees that bullying and suicide prevention for youth are very timely and significant topics. These suggestions have been noted and will be considered for future NSDUHs. Given the development and testing necessary to cover these new topics in NSDUH, and the need to keep the interview time to about 60 minutes, these new questions could be considered for the 2016 and later surveys.

The last organization listed as a commenter, The Campaign for Tobacco Free Kids, discussed survey items already included in the 2014 NSDUH DR, except for gathering smokeless tobacco brands. The NSDUH collects brands for cigarettes and cigars, but not smokeless tobacco. Due to trying to maintain a survey interview length of 60 minutes, the addition of this item in future NSDUH surveys may not occur. A copy of the original comments can be found in attachment T.

It is DHHS policy that all national surveys be reviewed by DHHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE). ASPE reviewed the Dress Rehearsal survey and provided one comment on the new sexual orientation question. Specifically, ASPE requested that the response options be modified to include both the terms "heterosexual" and "homosexual" for consistency. SAMHSA explained that although consistency is an important goal, sexual orientation is a sensitive topic that requires the use of terms that best reflect those actually used by respondents to describe their own sexual orientation.

SAMHSA cited the 2009 Williams Institute report *Best Practices for Asking Questions about Sexual Orientation on Surveys* which recommends using the following item for self-identification of one's sexual orientation:

> Do you consider yourself to be:
> a) Heterosexual or straight;
> b) Gay or lesbian; or
> c) Bisexual?

DHHS has cited the Williams Report recommendation as a potential source of survey questions regarding sexual orientation, sexual behavior, and sexual attraction. The Williams Institute item excludes the word "homosexual" from the response options.

In addition, it is generally recommended that the term "homosexual" be avoided because research has shown that respondents have significant confusion regarding its meaning.[3] It was also found that the term can be offensive to lesbian and gay respondents. SAMHSA provided this background information in support of the current format of the response category. ASPE accepted the justification and agreed that the question should not be revised.

9. Payment to Respondents

[3] Miller, K., & Ryan, J.M. (2011). *Design, Development and Testing of the NHIS Sexual Identity Question*. Questionnaire Design Research Laboratory, Office of Research and Methodology, National Center for Health Statistics.

Adult respondents (age 18 and over) and youth respondents (age 12 to 17) are given $30.00 in cash upon completion of the full interview. This respondent incentive is consistent with the current NSDUH incentive, which was approved by OMB on October 18, 2001, for use in the 2002 NSDUH survey. Prior OMB approval was provided for the continued use of the $30.00 incentive for the 2003-2013 NSDUH surveys.

The incentive is mentioned in the following respondent materials: NSDUH CAI Questionnaire Content (Attachment A), Lead Letter (Attachment B), Contact Cards – Sorry I Missed You & Appointment Cards (Attachment C), Study Description (Attachment D), Introduction and Informed Consent Scripts (Attachment E), Housing Unit and Group Quarters Unit Screening Questions (Attachment F), Question & Answer Brochure (Attachment G), Unable to Contact, Call Me, & Controlled Access Letters (Attachment H), Refusal Letters (Attachment I) and Interview Incentive Receipt (Attachment J).

10. Assurance of Confidentiality

Concern for the confidentiality and protection of respondents' rights has always played a central part in the implementation of the NSDUH and will likewise be given the utmost emphasis for the DR. The main study processes described in this section apply to the QFT and DR as well, with any differences noted.

The Contractor's Institutional Review Board (IRB) was granted a Federalwide Assurance (Attachment K) 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 has approved the protocols and consent forms for the main study and QFT, and will approve the protocols and consent forms for the DR prior to any respondent contact.

Several procedures ensure that respondents' rights are protected. First, the FI introduces himself/herself and the study using the Introduction and Informed Consent Scripts (Attachment E), reading the scripted text out loud to each interview respondent. These scripts were modified for the QFT and the DR to ensure that respondents are accurately informed about the study. The main study informed consent statement states that the individual respondent will represent thousands of others. We removed that statement, as the representativeness of each respondent differs in the QFT and DR samples.

As part of the process for obtaining informed consent, respondents are given a Study Description (Attachment D), 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 only be used by authorized personnel for statistical purposes and cannot be used for any other purpose. If a respondent is 12 to 17 years old, except in rare instances where a 17 year old lives independently from his/her parent or guardian in which case the 17 year old provides his/her own consent, parental consent is obtained from the selected respondent's parent or guardian; subsequently, youth assent is requested.

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 have completed CIPSEA training and signed a notarized Confidentiality Agreement (Attachment L). Because FIs working on the DR also conduct data collection for the main study, they will already have completed CIPSEA and project training on ensuring respondent confidentiality and will have signed a notarized Data Collection Agreement (Attachment L) certifying they will keep all respondent information confidential.

FIs make every attempt to secure an interview setting in the respondent's home that is as private as possible. In addition, by design the interview process 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 enter his or her own responses into the computer via the keyboard. At the end of ACASI, the respondent's answers are locked so no one can see the responses until after data are transmitted, processed, and aggregated by the Contractor.

Hard copy materials used during the course of the interview are marked for identification by the FI according to specific instructions. To further ensure confidentiality, the respondent's name, address, or other personally identifiable information are never noted. The one exception is the Quality Control Form (Attachment M), which the respondent is asked to voluntarily complete at the end of the interview. The FI explains the procedures in advance, asking the FI 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 for use only for verification purposes.

As mentioned above, completed interview files are locked once the FI exits the case, securing the data from view by the FI and unauthorized personnel. 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 identified only by a link number assigned to screenings and 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, are 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 (SDUs). The permanent sampling records show only the general location in which the interviews were conducted; there is no record of specific dwelling units contacted.

The software that was used to collect screening information in the QFT and will be used to collect screening information in the DR has been developed to match the specifications of the new screening device. The software functions largely the same as the main study software. The software used to conduct the interview is essentially the same as that used to collect main study data. The information collected for screening and interviewing is the same as the main study, with the exception of the minor changes noted in section A.1, and the controls used to protect that information are the same. The DR also makes use of the same data processing and webhosting infrastructure as the main study. As such, the most recent Privacy Impact Assessment (PIA), submitted to SAMHSA on December 5, 2012, applies to the main study, QFT, and DR.

This data collection is subject to the Privacy Act. (SAMHSA SORN (Covering NSDUH): 09-30-0036 and 09-30-0049). See http://www.samhsa.gov/About/systemrecords/index.aspx for more information.

11. Questions of a Sensitive Nature

Many of the 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 which assure confidentiality. 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/her own consent, verbal consent is obtained from both the parent or guardian and then the youth. (See Attachment E, 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.

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

As explained in section A.10, all CAI data are transmitted to the Contractor's servers via secure encrypted data transmission, and identified only by a link number assigned to screening and interview files. 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. The listing of SDU addresses are kept under secured conditions and destroyed after all data processing activities are completed.

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

12. Estimates of Annualized Hour Burden

For the DR, the sample has been designed to yield approximately 2,000 completed interviews. It will be necessary to screen approximately 3,673 households to obtain the requisite number of interviews. Based on the timing results from the QFT, it is estimated that the average amount of time required to administer the DR questionnaire will be approximately 60 minutes, including 2

minutes for completing the Quality Control Form (Attachment M). (The QFT questionnaire took an average of 59.53 minutes to administer.) It is not expected that the DR administration time will differ significantly from the QFT. Administration of the screening questions will take an average of 5 minutes per dwelling unit, the same length of time as in the main study and the QFT.

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

The data collection field period for the DR will be two months long, spanning September and October of 2013. The respondent burden for the DR is shown in Table 1 below. The hourly wage of $14.54 was calculated based on weighted data from the 2011 NSDUH respondents' personal annual income.

Table 1. Annualized Estimated Burden for 2013 NSDUH Dress Rehearsal

Instrument	No. of Respondents	Responses per Respondent	Hours per Response	Total Burden Hours	Hourly Wage Rate, $	Annualized Costs, $
Household Screening	3,673	1	0.083	305	14.54	4,435
Interview	2,000	1	1.000	2,000	14. 54	29,080
Screening Verification	100	1	0.067	6.7	14.54	97
Interview Verification	300	1	0.067	20	14.54	291
TOTAL	3,673			2,332		33,903

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 annualized costs associated with the DR preparation, data collection, analysis, and reporting are estimated to be $3,651,021. This includes approximately $2,971,251 for Contractor costs and $679,770 for SAMHSA costs to manage/administer the DR.

15. Changes in Burden

Currently there are 2,804 burden hours in the OMB inventory. SAMSHA is requesting 2,332 hours. The decrease of 472 burden hours is due to a revised estimate of survey administration time

for the interview. However, there is an increase in the number of respondents being screened due to the oversampling of high Hispanic interview areas in the DR.

16. Time Schedule, Publication and Analysis Plans

Screening and interviewing data from the DR will be compared with respondent data from the 2012 NSDUH, the third and Quarter 4 2013 NSDUH, and the QFT to assess the impact of the proposed questionnaire and protocol changes. Other substantive data will also be compared, such as item nonresponse rates, levels of inconsistencies between like items, and rates of drug use, to assess the level of editing and imputation that will be needed with the new questionnaire and to assess the accuracy of prevalence estimates. The results of these analyses, as well as all field test procedures, will be summarized in a report to be finalized by January 31, 2014. CBHSQ will use the information to finalize plans for the redesigned NSDUH protocol for 2015. The time schedule for the DR is provided in Table 2 below.

Table 2. Project Schedule for 2013 NSDUH Dress Rehearsal

Activity	Time Frame
Design area sample and select sample segments from retired listed segments	December 2012 to May 2013
Finalize data collection materials	January 2013
Select FIs to conduct data collection	January 2013 to June 2013
Develop and complete analysis plan	January 2013 to July 2013
Publish 60-day Federal Register Notice	February 2013
Develop and complete data processing plans	February 2013 to May 2013
Select dwelling units and prepare lists and maps	February 2013 to August 2013
Finalize screening and interview questionnaire specifications	March 2013
Publish 30-day Federal Register Notice	April 2013
Submit clearance package to OMB	May 2013
Finalize programming of screening and interview questionnaires	June 2013
Finalize FI training materials	August 2013
Obtain OMB Clearance	August 1, 2013
Conduct FI training sessions	August 2013
Conduct data collection	September 2013 to October 2013
Process data and prepare data files	September 2013 to January 2014
Conduct analysis and produce tables	November 2013 to January 2014
Complete final report	January 2014

17. Display of Expiration Date

The OMB expiration date will be displayed on all DR data collection instruments, including the CAI Questionnaire Content (Attachment A), Study Description (Attachment D), Housing Unit and Group Quarters Unit Screening Questions (Attachment F), In addition, the information will be included on the Quality Control Form (Attachment M).

18. Exceptions to Certification Statement

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