2008 National Survey on Drug Use and Health
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), sponsor of the National Survey on Drug Use and Health (NSDUH), requests approval to conduct the 2008 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 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 2008 survey will represent the twenty-eighth 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 prevalence of illicit substances and mental health problems, as well as the abuse of licit substances in the United States population.

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 essentially remain the same in 2008 as in 2007.

In December, 2006 a meeting of expert consultants was convened by the SAMHSA's Center for Mental Health Services (CMHS), SAMHSA, to solicit recommendations for mental health surveillance data collection strategies. 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+). A summary of this meeting is included in Attachment X. Approved funding for FY 2007 and proposed funding for FY 2008 to carry out these recommendations is documented at http://www.samhsa.gov/Budget/FY2008/SAMHSA08CongrJust.pdf (see page PM-2 or page 126 of 188). As an initial step, a small Feasibility Study was completed in June of 2007 to test procedures for collecting data on an expanded mental health screener module and for conducting follow-up telephone psychiatric interviews with 1500 selected respondents in 2008. OMB Clearance package for the Feasibility Study was submitted under the NSDUH Methodological Field Tests generic OMB clearance (OMB No. 0930-0261) on 04/19/2007 and approved on 5/18/07. Information from this Feasibility Study will inform the design and protocol development for a full calibration study to be conducted as an embedded split-sample follow-up study within the 2008 NSDUH. The results of this study will be summarized in a report to be sent to OMB as an addendum to the full 2008 submission.

Creating a robust, sustainable mental health surveillance system using the NSDUH as the household survey vehicle will require three essential elements: 1) appropriate screening and gold standard measures; 2) seamless procedures to transfer respondents from the NSDUH to the clinical interview section of the follow-up study and 3) appropriate analysis of the data. Since the mental health module follow-up study will be embedded within the 2008 NSDUH survey, this submission includes specific references to this study and materials are attached for OMB approval.

Two types of mental health screening measures will be embedded in the NSDUH audio computer-assisted survey interview (ACASI), and standard clinical interview measures will be administered by mental health clinicians over the telephone. The ACASI screening measures will include the K-6 nonspecific distress scale (Kessler et al, 2003), a brief suicidal ideation screen (Borges, et al, 2006), and two disability scales (the World Health Organization-Disability Assessment Scale (WHO-DAS) (Rehm et al, 1999) and the Sheehan Disability Scale (SDS) (Leon et al, 1997)). The mental health module questions are listed in Attachment B, page 334-341. Respondents will be randomly assigned to receive only one of the two disability scales in the ACASI.

The clinical interview measure to be used is the Structured Clinical Interview for DSM-IV-TR Axis I Disorders Non-patient Edition (SCID-I/NP, 1/2007 revision) (First, M; Spitzer, R; Gibbon, M; & Williams, J; 2007). Recommended by the expert consultants, the SCID I/NP has been used for clinical calibration in several other studies such as the National Comorbidity Survey-Replication (NCS-R) (Kessler et al, 2004); the National Survey of American Life (Jackson et al, 2004), and the NSDUH substance use disorders clinical reappraisal study (Jordan et al, 2003). Dr. Michael B. First, author of the SCID interview, has been the primary expert consultant on all matters associated with the adaptation and use of the SCID in the follow-up study. Adaptations of the SCID included modifying (shortening) the interview to assess mental disorders in the past 12 months (removing items used to assess lifetime disorder) and insuring each module is in the appropriate format for telephone administration.

Field interviewers will administer the NSDUH questionnaire via computer assisted interviewing (CAI) using standard protocols (see section 2 - Use of Information Technology). At the end of the CAI interview, field interviewers will attempt to recruit designated respondents into the follow-up study using the on-screen scripts created for this purpose (Attachment B, pages 442-443). Those that agree to participate will be given $30 that day and phone and email contact information will be collected so that the clinical interviewer may reach them in the following one to two weeks to do the SCID interview. Respondents will be asked to identify best days and times for the interviewer to call. Respondent first name, phone number, email address and “best time to call” information will be shared, via a secure website, with the clinical interviewer who will then schedule and conduct the interview. For reference, the clinical interviewer will also receive the date and time of the initial interview, along with the Record of Call history for the case. Recognizing the tremendous importance of confidentiality with regard to the NSDUH, no other information about the respondents will be provided to clinical interviewers. Clinical interviewers trained in administering the SCID will be recruited to participate in the follow-up study. These clinical interviewers will be certified by SCID experts and will be provided

supervision throughout the 2008 NSDUH data collection year to maintain the integrity and reliability of clinical assessment and to resolve any clinical issues or questions that emerge throughout the study period.

Clinical interviewers hired for this study must be certified before administering the SCID. Volunteer respondents will be recruited from mental health treatment centers and paid $40 for participating in a telephone SCID interview, which, with the respondents' consent, will be audio-taped. An expert in the SCID will listen to the audio-taped interview and review the paper SCID to determine whether the clinical interviewer administered the instrument properly. Up to fifty clinical interviewers and supervisors will be recruited and will be given up to three chances to pass the certification, and so up to 150 respondents will be needed for the certification. These respondents will not complete the initial NSDUH interview, they will only receive the SCID interview. The SCID interview takes an average of one hour to complete.

Clinical interviewers will telephone respondents to conduct the clinical interview based on the availability information provided in the initial interview. Clinical interviewers will record identification numbers and responses on a paper and pencil version of the SCID and, with the respondent's permission, will audio record the interview. Clinical interviewers will forward the paper SCID to experts in the SCID administration for a QC review. Clinical interviewers will also upload the completed audio recordings to a secure project server for the SCID experts to download for QC purposes. After this QC step, the paper SCID will be sent to RTI for data entry and the audio recording will be deleted. This process will be conducted in a timely manner (at least weekly)**.**

The sample design for 2008 will be the same as it was for the 2007 CAI sample in that it will be large enough to facilitate the reporting of drug use 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. Approximately 1,500 clinical follow-up interviews will be completed during 2008, with approximately 375 completed per quarter. (see Exhibit 1 in Attachment N). Embedding the follow-up study in the regular sample provides much more freedom to sample persons for 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 is considered 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 provide current data on substance use prevalence for the total U.S. population as well as each state, and to issue reports on survey results. The sample will support annual direct estimates of prevalence for the eight largest states, and model-based estimates for the remaining 42 states and the District of Columbia. The data will also update existing information on patterns and correlates of substance use.

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 prevalence of substance use, 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, this survey will ensure that SAMHSA and other Federal, State, and local agencies will have timely data available for release by late summer of 2009. 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 on past month substance use among youth (12-17) are also used as a GPRA measure for the Centers for Application of Prevention Technologies and the State Incentive Grant programs of the Center for Substance Abuse Prevention. The NSDUH will also be used to address the needs of the National Outcome Measures (NOMS) project, a SAMHSA performance-based management initiative that involves tracking a set of key outcome measures at the National and State levels annually. Discussions between SAMHSA and the States have identified specific NSDUH variables to be tracked under this system. Among them are:

1. Abstinence from tobacco use
2. Abstinence from alcohol use
3. Abstinence from marijuana use
4. Abstinence from use of all other illicit substances
5. Perceived risk of binge alcohol – youth
6. Perceived risk of tobacco use – youth
7. Perceived risk of marijuana use – youth
8. Age of first use – tobacco – youth
9. Age of first use – alcohol – youth

10. Age of first use – marijuana – youth
11. Age of first use – use of all other illicit substances - youth
12. Knowledge/consequences of workplace drug policies – adult
13. Parental communication about drugs and alcohol
14. Adolescent communication with parent(s) about drugs and alcohol
15. Perceived disapproval – youth
16. Exposure to prevention messages – youth
17. Alcohol-related car crashes and injuries – ages 16+

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. CMHS will use data from the mental health calibration 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 2005-2007 NSDUHs, and will be included in the 2008 NSDUH as well. A detailed discussion of changes for the 2008 questionnaire is presented in section B.2 below.

For 2008, 30 day versions of the K-6 questions were added, along with the disability scale(s) and suicidal ideation questions. These proposed additional questions will only be asked of respondents ages 18 and over. To offset these new questions, the questions regarding displacement after hurricane Katrina were deleted, and the shorter version of the income questions evaluated through a split sample design in 2006 and 2007 was adopted for the entire sample. One final addition for 2008 is the routing through the Substance Dependence and Abuse module of users of emerging drugs picked up in the Special Drugs module.

3. Use of Information Technology

The NSDUH study has been administered via computer-assisted interviewing (CAI) since 1999. The 2008 interview will be administered using audio computer-assisted self-interview (ACASI) for the more sensitive questions, representing most of the interview; the remainder of the interview will be administered using computer-assisted personal interviewing (CAPI).

The CAPI/ACASI technology affords a number of improvements 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 improvement 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 does make reporting of potentially embarrassing, stigmatizing, and illegal behaviors (e.g., drug use, sexual behaviors) less threatening and enhance response validity and response rates.

The 2008 NSDUH will 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 follow-up 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 2008 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 in 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 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.

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 this one 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 May 3, 2007 (72 FR 24592-24593) solicited one comment on the 2008 NSDUH. The comment was received from the New York State Office of Alcoholism and Substance Abuse Services NYS (OASAS). The letter from OASAS, along with SAMHSA's response, is in Attachment Z. In summary, OASAS is asking that various questions on cigarettes, alcohol, cocaine, prescription drugs, risk/availability, substance abuse and dependence, special topics, prior use, adult mental health utilization, and mental health be revised. SAMHSA's response indicated that these specific questions are kept constant from one year to the next so that comparable data can be captured over time. Measurement of trends in the NSDUH is critical to our understanding the progress made in our effort to reduce the use of alcohol, tobacco, and illegal drugs in the U.S and also to track mental health issues in the U.S. population. Thus, unless there is a significant error, we are reluctant to modify the questionnaire wording for these questions until a planned redesign takes place (currently planned for 2012, pending approval from management within the Department of Health and Human Services, ONDCP, and OMB)

When this occurs, these issues will be considered and laboratory tested before any such change is implemented.

OASAS also questioned the accuracy of answers from respondents who are not computer literate or may have trouble completing the questionnaire using the computer. SAMHSA's response indicated that the ACASI program does not require respondents to be computer literate, and, while the interviewer is not entering data during the ACASI section of the interview, they are trained to remain attentive in case any respondent encounters a problem with the interview.

It is DHHS policy that all national surveys are reviewed by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The review was coordinated by Dale Hitchcock, Director, Division of Data Policy, Office of Science Policy, ASPE, (202) 690-7100. The DHHS Data Council has been kept informed about the status and plans for the 2008 NSDUH.

The following persons were consulted during 2006 and 2007 concerning plans for the mental health module follow-up study. These persons provided input on the specific diagnostic tool for follow-up clinical interview, and commented on the overall study design. Appendix A of the Supporting Statement contains a listing of additional current consultants on the main NSDUH questionnaire.

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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 2003-2007 NSDUH surveys. The weighted overall response rates for 2003, 2004, 2005 and 2006 were 71%, 70%, 70%, and 68%, respectively.

The 2008 NSDUH calls for a similar 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).

The telephone interview to be completed for the follow-up study 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. Furthermore, to maintain adequate

response rates, SAMHSA believes it is necessary to provide the $30 incentive at the end of the initial (NSDUH) interview, once the participant agrees to the follow-up interview. Research studies have shown that providing incentives before the interview increases the likelihood that participants will complete the interview (Groves & Couper, 1998). This additional incentive will be given only to the 1500 respondents who complete the follow-up 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. Almost by definition, the audio computer-assisted self-interview (ACASI) version 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 and is invited to voluntarily accompany the interviewer to a mailbox. 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 secured 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 tape, 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 follow-up study 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 follow-up study. 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, phone number, and email addresses 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, phone number, and email address will be collected within the main interview, it will be used only for re-contact purposes. Once the CAI data is transmitted and arrives at RTI, the respondent's name, phone number, email address 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 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 follow-up study.

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 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. Verbal parental consent is obtained for respondents between the ages of 12 and 17 years old. (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 solicited 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, telephone number and email address and that this identifying information will be discarded by the clinician after the interview has been completed. 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 experts in the SCID administration for a QC review by. After this QC step, the paper SCID will be sent to RTI via Federal Express for data entry. All paper SCIDs and audio recordings will be destroyed at the end of the study.

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

- Pointsec 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 allows 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 strongly 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) 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.

Any audio files downloaded to a project-issued laptop for review will be deleted as soon as review of that audio file has been completed. All audio recordings will be erased (from RTI file servers and project-owned laptops) by June 30, 2009.

12. Estimates of Annualized Hour Burden

The total sample size for the 2008 National Survey is approximately 67,500 persons. The 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 182,250 households to obtain the requisite survey sample size.

The experience with the first quarter of 2007 indicated that the average interview time was approximately 60 minutes. The minimal number of Sheehan Disability and suicidal ideation questions added to the 2008 CAI instrument will have no significant impact on timing. The WHO-DAS questions, however, may add up to another minute to the overall questionnaire administration time.

Based on the 2008 questionnaire having roughly the same length, it is estimated that the average amount of time required to administer the 2008 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. 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 that 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 followup.

The hourly wage of $14.02 was calculated based on weighted data from the 2006 NSDUH respondents' personal annual income.

The data collection field period for the 2008 NSDUH is 12 months long, spanning the period from January through December, 2008. The respondent burden for the 2008 NSDUH is shown in the following table:

Estimated Burden for 2008 NSDUH

Instrument	*No. of Respondents*	*Responses per respondent*	*Hours per response*	*Total burden hours*	*Hourly Wage rate*	*Annualized hourly costs*
Electronic Screening	182,250	1	0.083	15,127	$14.02	$212,081
Questionnaire and Verification Form	67,500	1	1.000	67,500	$14.02	$946,350
Clinical Follow-up Certification	150	1	1.000	150	$14.02	$2,103
Follow-up Interview	1,500	1	1.000	1,500	$14.02	$21,030
Screening Verification	5,494	1	0.067	368	$14.02	$ 5,159
Interview Verification	10,125	1	0.067	678	$14.02	$9,506
TOTAL:	182,400			85,323		$ 1,196,229

13. Estimates of Annualized Cost Burden to Respondents

There are neither capital or startup costs nor are there any operation and maintenance costs to respondents.

14. Estimates of Annualized Cost to the Government

Total costs associated with the 2008 National Survey on Drug Use and Health is estimated to be $54,904,461 over a 40-month contract performance period. Of the total costs, $51,404,461 is for contract costs, e.g., sampling, data collection, processing, reports, etc., and approximately $3,500,000 represents SAMHSA costs to manage/administrate the survey. The annualized cost is approximately $16,471,344. This represents a total increase in contract costs from the 2007 survey to the 2008 survey of approximately $6,000,000. The major reason for this increase is the purchase of all new equipment for use beginning in 2009, including costs for testing the equipment in a 2008 field test. This field test will be in addition to the existing field test planned for 2008 - the mental health surveillance study field test. Contract costs also rose due to gas price increases, resulting in increased mileage reimbursement, increased rental car costs, and increased airfares, and the need for additional interviewing resources to overcome declining response rates.

Total costs associated with the follow-up study are estimated to be $1,989,292 over a 40-month performance period. Of the total costs, $1,489,292 is for contract costs, e.g., sampling, data collection, processing, reports, etc., and approximately $500,000 represents SAMHSA costs to manage/administrate the survey. The annualized cost is approximately $596,784.

15. Changes in Burden

Currently there are 83,673 hours in the 2007 OMB inventory. The NSDUH is requesting 85,323 hours for the 2008 NSDUH, which is a program change increase of 1,650 hours from the 2007 NSDUH. The increase in hours is a result of the addition of the embedded follow-up study.

16. Time Schedule, Publication and Analysis Plans

Plans for the 2008 Survey data involve four major types of products, i.e., an early report that presents results from the 2008 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 most publications, follow.

RESULTS FROM THE 2008 NSDUH (September, 2009) - This report will present highlights and detailed findings from the 2008 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 prevalence in 2008, 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; however, based on the nature of this report it is understood that additional quality control checks instituted after its distribution may result in adjusted data.

STATE DATA REPORT (Early, 2010) - A state data report (approximately 75-100 pages) will present substance use prevalence estimates for each of the 50 states and the District of Columbia. It will also document the methodology in detail.

ANALYTIC REPORTS. Additional data analyses and special analytical papers will be produced and released as part of the SAMHSA, Office of Applied Studies (OAS) Analytic Series or A report series. Reports of findings from the follow-up study 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, detailed tabulations on respondents' substance abuse experiences, beliefs and attitudes, and documented data tapes of the entire file also will be produced and made available to those requesting such information.

2008 NSDUH PROJECT SCHEDULE

ACTIVITY	*TIME FRAME*

Design and select area frame sample	December 2006 to March 2007
Prepare field Segment Kits	January 2007 to April 2007
Recruit/train field staff to list Sample Dwelling Units (SDUs)	March 2007 to April 2007
Field listing and subsequent keying of SDUs	April 2007 to January 2008
Feasibility Study Report	August 2007
CIPSEA Language Study Testing Report	August 2007
Recruit remaining field staff and generate all required materials/assignments for distribution	August 2007 to January 2008
Finalize programming of NSDUH interview	August 2007 to October 2007
Prepare for and conduct field staff training	August 2007 to January 2008
Conduct NSDUH interviews	January 2008 to December 2008
Data processing and file preparation	January 2008 to March 2009
Trend Tables and Special Tabulations:	
-- Shells	March 2009
-- Annual	June 2009
Raw Data Files	May 2009
Preliminary Weighted Data Files	May 2009
Final analytic data tape and documentation	September 2009
Sampling Error Report	July 2009
Mental Health Module Analysis Report	August 2009
National Findings	August 2009
State Small Area Estimation Analytical Report	August 2009 to March 2010
Public Use Data File	December 2009
Methodological Resource Book	March 2010

17. <u>Display of Expiration Date</u>

The expiration date will be displayed.

18. <u>Exceptions to Certification Statement</u>

The certifications are included in this submission.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The respondent universe for the 2008 NSDUH study is the civilian, noninstitutionalized population aged 12 years old and older within the 50 states and the District of Columbia. Consistent with the NSDUH designs since 1991, the 2008 NSDUH universe includes residents of noninstitutional group quarters (e.g., shelters, rooming houses, dormitories), residents of Alaska and Hawaii, and civilians residing on military bases. Persons excluded from the universe include those with no fixed household address, e.g., homeless transients not in shelters, and residents of institutional group quarters such as jails and hospitals.

The 2008 sample design will consist of a stratified, multi-stage area probability design (see Attachment N for a detailed presentation of the sample design). As with most area household surveys, the 2008 design will offer the advantage of minimizing interviewing costs by clustering the sample. This type of design also maximizes coverage of the respondent universe since an adequate dwelling unit and/or person-level sample frame is not available. Although the main concern of area surveys is the potential variance-increasing effects due to clustering and unequal weighting, these potential problems will be directly addressed with the 2008 design by selecting a rather large sample of clusters at the early stages of selection and by selecting these clusters with probability proportionate to a composite size measure. This type of selection maximizes precision by allowing one to achieve an approximately self-weighting sample within strata at the latter stages of selection. Furthermore, it is attractive because due to the design of the composite size measure, the interviewer workload will be roughly equal among clusters.

A coordinated five-year design was developed for the 2005-2009 NSDUHs. The sample selection procedures began by geographically partitioning each state into roughly equal size state sampling (SS) regions; i.e., regions were formed so that each area would yield, in expectation, roughly the same number of interviews during each data collection period. This partition divided the United States into 900 SS regions. Within each of these SS regions, a sample of Census tracts was selected. Then, within sampled Census tracts, smaller geographic areas, or segments, were selected. In general, segments consisted of adjacent Census blocks and are equivalent to area segments selected at the second stage of selection in NSDUHs prior to 1999 and at the first stage of selection in the 1999-2004 NSDUHs. The additional stage of selection (i.e. Census tracts) ensures that the majority of sample segments are contained within a single tract's boundaries, thus improving the ability to match to external data. In summary, the first stage stratification for the 2008 study will be states and SS regions within states, the first stage sampling units will be Census tracts, and the second stage sampling units will be small area segments. This design for the 2005-2009 NSDUHs at the first stages of selection is desirable because of (1) the much larger person-level sample required at the latter stages of selection in the design and (2) the increased interest among NSDUH data users and policy-makers in state and other local-level statistics.

The coordinated 5-year design facilitates 50 percent overlap in second stage units (area segments) between each two successive years from 2005 through 2009. The expected precision of difference estimates generated from consecutive years, (e.g., the year-to-year difference in past month marijuana use among 12-17 year old respondents) will be improved because of the expected positive correlation resulting from the overlapping sample.

Similar to previous NSDUHs, at the latter stages of selection, five age group strata will be sampled at different rates. These five strata will be defined by the following age group classifications: 12-17, 18-25, 26-34, 35-49, and 50 years old and over. We project that adequate precision for race/ethnicity estimates at the national level will be achieved with the larger sample size and the optimal allocation to the age group strata. Consequently, race/ethnicity groups will not be over-sampled. However, consistent with previous NSDUHs, the 2008 NSDUH will be designed to over-sample the younger age groups.

Table 1 in Attachment N shows main study sample sizes and projected number of completed interviews by sample design stages. **Table 2** (Attachment N) shows main study sample sizes by state and projected number of person respondents by state and age group[1]. **Table 3** (Attachment N) shows the expected precision for national estimates; **Table 4** (Attachment N) shows the expected precision for direct state estimates.

The follow-up study sample will be embedded within the main study. **Exhibit 1** shows that approximately 1,961 main study respondents will need to be selected to yield a total of 1,500 completed follow-up interviews. This is assuming a 90% agreement rate and an 85% participation rate for follow-up interviews.

2. Information Collection Procedures

Prior to the interviewer's arrival at the sample dwelling unit (SDU), a letter will be mailed to the resident(s) briefly explaining the survey and requesting their cooperation. This letter will be printed on Department of Health and Human Services letterhead with the signature of the DHHS National Study Director and the Contractor's National Field Director (see Attachment D).

Upon arrival at the SDU, the interviewer will refer the respondent to this letter and answer any questions. If the respondent has no knowledge of the lead letter, the interviewer will provide another copy, explain that one was previously sent, and then answer any questions. If no one is at home during the initial call at the SDU, the interviewer may leave a Sorry I Missed You card (Attachment E) informing the resident(s) that the interviewer plans to make another callback at a later date/time. Callbacks will be made as soon as possible. Interviewers will attempt to make at least four callbacks (in addition to the initial call) to each SDU in order to complete the screening process and obtain an interview.

If the interviewer is unable to contact anyone at the SDU after repeated attempts, the

[1] Five age groups actually will be used for the 2008 design so that somewhat lower sampling rates are applied to persons 50+ years old than to those 35-49 years old. Only four age groups are shown in Tables 2 and 3.

interviewer's Field Supervisor may send an Unable to Contact (UTC) letter. The UTC letter re-iterates information contained in the lead letter and presents a plea for the respondent to participate in the study (See Attachment Q for all UTC letters). If after sending that letter an interviewer is still unable to contact anyone at an SDU, another informational letter (See Attachment R) may be sent to the SDU requesting that the resident(s) call the Field Supervisor as soon as possible to set up an appointment for the interviewer to visit the resident(s).

As necessary and appropriate, the interviewer may make use of the Appointment Card (Attachment F) for scheduled return visits with the respondent. When an in-person contact is made with an adult member of the SDU and introductory procedures are completed, the interviewer will present a Study Description (Attachment G) and answer questions if required. Assuming respondent cooperation, a screening of the SDU then will be initiated through administration of the Housing Unit Screening questions for housing units, or the Group Quarters Unit Screening questions for group quarters units. The screening questions are administered via a hand-held, pen-based computer, which also performs the subsequent sample-selection routines. A paper representation of the housing unit and group quarters unit screening process is shown in Attachment H.

If a potential respondent refuses to be screened, the interviewer is trained to accept the refusal in a positive manner, thereby avoiding the possibility of creating an adversarial relationship and precluding future opportunities for conversion. A refusal letter may then be sent by the Field Supervisor. The refusal letter sent is tailored to the specific concerns expressed by the potential respondent and asks him/her to reconsider participation (See Attachment S for all refusal letters). An in-person conversion is then attempted either by supervisory field staff or specially selected interviewers with established conversion records. If the respondent proceeds with the screening process, the interviewer answers any questions that the screening respondent may have concerning the study. A Question & Answer Brochure (Attachment I) that provides answers to commonly asked questions also may be given to the respondent at this time. In addition, interviewers will be supplied with copies of the Example NSDUH Highlights (Attachment J) and the Example NSDUH Newspaper Clippings (Attachment K) which can be left with the respondent. Following this introductory exchange, the screening will continue until completion.

Once the rostering of all dwelling unit members 12 or older is complete, and assuming the within dwelling unit sampling process selects one or two members to participate in the study by completing the interview, the following procedures are implemented:

If the selected individual is 18 or older and currently available, the interviewer moves immediately to begin administering the questionnaire in a private setting within the dwelling unit after obtaining informed consent. If the selected individual is 12 to 17 years of age, parental consent is obtained from the selected individual's parent or legal guardian, using the Introduction and Informed Consent for Sample Members Age 12-17 Years Old found in the Showcard Booklet (Attachment L); the minor is then asked to participate. Once consent is obtained from the parent and child, the interviewer begins the interview process.

For all identified/selected eligible potential respondents, the interviewer administers the interview in a prescribed and uniform manner. The sensitive/self-administered portions of

the interview will be completed via ACASI; that is, the respondent will listen privately to the questions through an audio headset and/or read them on the computer screen, and will enter his/her own responses directly into the computer. This method maximizes respondent privacy and confidentiality.

In order to facilitate the respondent's recollection of prescription type drugs and their proper names, a set of color pillcards is provided to the respondent at the appropriate time. These pillcards and other showcards are included in the Showcard Booklet (Attachment L) and allow the respondent to refer to information necessary for accurate responses. The respondent enters his/her own answers directly into the computer during the ACASI interview.

After the interview is completed and before the verification procedures are begun, each respondent is given a $30.00 incentive payment and a Field Interviewer-signed Interview Payment Receipt (Attachment O).

For verification purposes, interview respondents are asked to complete a Quality Control Form (Attachment C) that requests their address and telephone number for possible follow-up to ensure that the interviewer did his/her job appropriately. Respondents are informed that completing the Quality Control Form is voluntary. This form is completed and placed in an envelope by the respondent and mailed to the NSDUH Contractor for processing.

Interviewers will be supplied with Certificates of Participation (Attachment P) to distribute to interested respondents, primarily adolescents, after the interview is completed. Respondents may attempt to use these certificates to earn school or community service credit hours. No guarantee of credit is made by SAMHSA or the Contractor and the certificates clearly state this lack of guarantee.

A random sample of those who complete Quality Control Forms receive a telephone call expressing appreciation for their participation in the study. Each respondent also is asked to answer a few questions verifying that the interview took place, that proper procedures were followed, and that the amount of time required to administer the interview was within expected parameters. Quality Control letters are mailed when telephone numbers are unavailable (see Attachment M). In previous NSDUH surveys, less than 1 percent of the verification sample refused to fill out Quality Control Forms. As in the past, the respondents are given the opportunity to decline to complete the form. Respondents are invited to travel with the interviewer to the nearest mail box to verify that the envelopes are immediately mailed.

All interview data are transmitted to the Contractor’s offices on a regular basis.

For those respondents randomly selected to participate in the follow-up interview, after completing an initial NSDUH interview, the field interviewer will read CAPI scripts describing the follow-up interview process to the respondent. These recruitment scripts are provided in Attachment B, pages 442-443. The respondent as well as the interviewer will be unaware that the respondent will be asked to complete another interview until these scripts are activated within the CAI program. If the respondent refuses to complete the

follow-up interview at recruitment or at the time of the follow-up clinical interview, the field or clinical interviewer will not recontact the household again.

The respondent will be given a copy of the Follow-Up Study Description (Attachment T) during this recruitment process, and the interviewer will try to collect the respondent's phone number, email address and best days of the week and times of the day for a clinical interviewer to complete the follow-up interview. This contact information will be entered into the password-protected laptop. All respondents that agree to participate in the follow-up interview will receive a $30.00 cash payment and a field interviewer-signed Follow-up Interview Payment Receipt from the interviewer (Attachment W).

The selected follow-up interview respondent will also be read an introductory informed consent script (Attachment U) by the clinician, prior to any follow-up interview data collection.

Questionnaire

The version of the questionnaire to be fielded in 2008 is a computerized (CAPI/ACASI) instrument that is almost identical in content and structure to the computerized instrument fielded in 2007. The only changes made are noted below under 2008 NSDUH CAPI/ACASI Questionnaire Content.

The NSDUH questionnaire and interview methods are designed to retain respondent interest, ensure confidentiality, and maximize the validity of response. The questionnaire is administered in such a way that interviewers will not know respondents' answers to the sensitive questions, including those on illicit drug use. These questions are self-administered (ACASI), that is, respondents listen to or read the questions and enter their responses directly into the computer. The respondent listens in private through headphones, so even those who have difficulty seeing or reading are able to complete the self-administered portion.

The questionnaire is divided into sections based on specific substances or other main topics. The same questions are asked for each substance or substance class, ascertaining the respondent's history in terms of age of first use, most recent use, number of times used in lifetime, and frequency of use in past 30 days and past 12 months. These substance abuse histories allow estimation of the prevalence of use, patterns of use and discontinuing substance use.

Topics that are administered by the interviewer (CAPI) include Demographics, Health Insurance, and Income. For the Income and Health Insurance sections, respondents will be asked if there is anyone else at home who would be better able to provide accurate answers.

The questionnaire for 2008 is founded on the CAI instrument that was first implemented for the 1999 NSDUH. While the mode changed in 1999, the content is based on the 1994 questionnaire, which resulted from a series of methodological studies and discussions with consultants. Additional methodological testing was completed in preparation for the conversion to computer-assisted interviewing. The questionnaire incorporates improvements in question wordings (e.g., clearer definitions, less vague terminology,

elimination of hidden questions) and questionnaire structure (e.g., greater use of skip patterns, improved formatting for the benefit of interviewers and respondents). Enhanced instructions regarding the reference periods used (i.e., past 30 days, past 12 months) also were added, including a paper reference date calendar to facilitate the respondent's accurate recall of events. A key feature of the questionnaire is a core-supplement structure. A set of core questions that are critical for basic trend measurement of substance use prevalence rates will remain in the survey every year and comprise the main part of the questionnaire. Supplemental questions, or modules, which can be revised, dropped or added from year to year comprise the remainder of the questionnaire.

The core is comprised of the initial demographic questions and the Tobacco through Sedatives modules. Supplemental items include the remaining modules and demographic and health questions. Some of the supplemental portion of the questionnaire is likely to remain in the survey, essentially unchanged, every year (e.g., insurance).

The follow-up interview is the Structured Clinical Interview for DSM-IV- TR Axis I Disorders Non-patient Edition (SCID-I/NP, 1/2007 revision), which screens for:

1 Major Depressive Episode
2 Manic Episode
3 Dysthymic Episode
4 Substance Use Disorders
5 Psychotic Episode
6 Bipolar Disorder
7 Anxiety Disorder
8 Phobias
9 Obsessive/Compulsive Disorder
10 Posttraumatic Distress Syndrome
11 Eating Disorders
12 Impulse Control Disorders
13 Adjustment Disorders

A paper representation of the follow-up SCID interview is found in Attachment V.

2008 NSDUH CAPI/ACASI Questionnaire Content

The proposed questionnaire content for 2008 is shown in Attachment B. While the actual administration will be electronic, the document shown is a paper-representation of the content that is to be programmed. Items that are new or revised for 2008 appear as shaded text. Items deleted from the 2007 questionnaire for 2008 are shown with strikeouts. Those items that appeared in the 2007 NSDUH but have been modified in 2008 are so noted in Attachment B. A summary of the significant modifications for the 2008 NSDUH instrument follows.

1. Expanded Mental Health module. The name of the Psychological Distress module will be changed to Mental Health module, and will be expanded to include a 30-day version of the K-6 (NERVE30-WORST30, Attachment B, Pages 334-335), a shortened version of the WHO-DAS (LIKERT-LIAD68, Attachment B, Pages

336-339), Sheehan Disability Scale (MHAD66a-MHDAYS, Attachment B, Page 339-340), and a suicidal ideation screen (SUI01-SUI05, Attachment B, Page 340-341). All adult respondents will receive the expanded K-6 and suicidal ideation questions. Half of the adult sample will receive the WHO-DAS Scale, while the other half of the adult sample will receive the Sheehan Scale.

2. On-screen pillcards for Ambien and Adderall updated. The pillcards displayed on-screen for questions SD20 and SD21 (Lifetime use of Adderall and Ambien, respectively) have been updated to include new dose levels.

3. Universe Update in Substance Dependence and Abuse module. The Adderall, Ambien and the additional hallucinogens users identified in the Special Drugs module will be routed into the Substance Dependence and Abuse module.

4. Hurricane Questions in Back-end Demographics deleted. The questions regarding displacement after Hurricanes Katrina and Rita (QD13d-QD13f, Attachment B, Pages 387-388) were deleted.

5. Reduced Set of Income Questions Adopted. A split-sample study, embedded within the 2006 and 2007 NSDUHs, compared a shorter version of the income questions with the original, longer version previously used. The study showed no difference in response patterns when the shorter version was used. This shorter version will be adopted for the 2008 NSDUH and future NSDUH surveys.

6. Follow-up Interview Recruitment Screens modified. Information from the June Feasibility study was used to modify and reformat the follow-up interview recruitment screens at the end of the CAI questionnaire (RECRUIT1 – THANKR2, Pages 442-443).

The remaining modular components of the 2008 questionnaire will remain essentially unchanged from the 2007 version.

As in past years, two versions of the instrument will be prepared: an English version and a Spanish translation. Both versions will have the same content.

3. Methods to Maximize Response Rates

In 2005, the weighted response rates were 91% for screening and 76% for interviews, with an overall response rate (screening * interview) of 70%. With the continuation of the $30.00 incentive for the 2008 survey year, the Contractor expects the response rates for 2008 to be about the same as the 2005 through 2007 rates.

With a $30.00 incentive for the initial interview and an additional, up-front $30.00 incentive for the follow-up interview, the Contractor expects to obtain a 70% interview response rate (IRR) for initial interviews and an 85% IRR for follow-up interviews. An overall response rate (ORR) of 54% is expected for the embedded follow-up study.

The field interviewers will not be recontacting households to convert follow-up interview

refusals, but they will be trained to answer respondent questions at the time of recruitment as appropriate.

To maximize clinical interview response rates, the clinical interviewers will use the best day/best time information obtained by the field interviewer to schedule interviews, but they will also be flexible in scheduling a time for the follow-up interview that is convenient to the respondent. If a respondent is unavailable when the clinician calls to complete the follow-up interview, the clinician will schedule a callback appointment. Clinicians will be trained to thoroughly explain the study, its purpose, and answer questions from respondents.

4. Tests of Procedures

The additional disability and suicidal ideation questions are patterned after questions that have already appeared in the questionnaire in previous years, thus, they will not require cognitive testing.

On November 9, 2006, the OMB approved SAMHSA's Office of Applied Studies (OAS) as a statistical unit. As a result, OAS is now required to follow the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) implementation guidelines in their sponsored surveys, including the NSDUH. Various NSDUH materials that are read to or by the respondent, including the lead letter, study description, and question and answer brochure, have been revised to incorporate the CIPSEA language. These revised materials are to be fully implemented in the 2008 NSDUH. On June 22, 2007, the OMB approved a cognitive interviewing study to evaluate how well potential NSDUH respondents would understand the materials. Primarily, the study was undertaken to see whether respondents would notice a difference between the current and revised materials and if so, how the revisions would 1) change their decision to respond to the survey and 2) change their response to the questions within the survey. Qualitative cognitive interview data from 24 participants was analyzed and the results showed that the revised materials had no impact on respondents' answers, and respondents had no problems understanding the new materials. The final cognitive testing report is included as Attachment AA.

5. Statistical Consultants

The basic NSDUH design was reviewed by statistical experts, both within and outside SAMHSA. Statistical experts reviewing the 1999-2008 survey designs include William Kalsbeek, Ph.D., University of North Carolina, Robert Groves, Ph.D., University of Michigan, and Michael Hidiroglou, Ph.D., Statistics Canada. Monroe Sirken, Ph.D., National Center for Health Statistics (NCHS), James Massey, Ph.D., (deceased) also of NCHS, and Douglas Wright, Mathematical Statistician, Division of Population Surveys, OAS, SAMHSA were consulted on the 1992 and subsequent survey designs. Arthur Hughes, Mathematical Statistician, Division of Population Surveys, OAS, SAMHSA is the Government Project Officer, (240) 276-1261. Joseph Gfroerer, Director, Division of Population Surveys, OAS, SAMHSA is the primary mathematical statistician responsible for overall project management, (240) 276-1262. RTI statisticians contributing to the design are Dr. James Chromy, Senior Fellow and Director of Statistical Operations and Dr. Ralph Folsom, Chief Scientist and Director of Small Area Estimation.

The 2005–2009 National Survey on Drug Use and Health contract was awarded to Research Triangle Institute (RTI) on December 19, 2003. RTI key personnel on this contract are:

Mr. Thomas Virag, Project Director	(919) 485-5732
Mr. Lanny Piper, Associate Project Director	(919) 541-6010
Mr. David Cunningham, National Field Director	(919) 485-2612
Dr. James Chromy, Director of Statistical Operations	(919) 541-7019
Dr. Ralph Folsom, Director of Small Area Estimation	(919) 541-6248
Ms. G.G. Frick, Director of Data Processing	(919) 541-6002
Ms. Jeanne Snodgrass, Director of Instrumentation	(919) 541-7365
Ms. Allison McKamey, Director, Training Programs and Field Materials	(336) 643-8338
Ms. Lisa Packer, Director of Analysis and Table Production	(919) 541-6633
Dr. Mary Ellen Marsden, Director of Report Generation	(781) 259-0923
Mr. Joe Murphy, Director, Methodological Issues and Special Analysis	(312) 456-5261
Dr. Kimberly Ault, Task Manager, Imputation and Weighting	(919) 541-7455

Contractor personnel will implement the sample design, recruit field staff, train interviewers, conduct data collection, data receipt/editing/coding/keying, data analysis, and develop statistical reports. SAMHSA will provide direction and review functions to the Contractor. Data collection will be conducted throughout the 2008 calendar year.

Appendix A

Current NSDUH Consultants

a. Consultants on NSDUH Design

Michael Arthur, Ph.D., Project Director (206) 685-3858
Social Development Research Group
University of Washington

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ATTACHMENTS

Attachment A - Federal-Wide Assurance

Attachment B - CAI Questionnaire Content

Attachment C - Quality Control Form

Attachment D - Lead Letter to Selected Dwelling Unit

Attachment E - Sorry I Missed You Card

Attachment F - Appointment Card

Attachment G - Study Description

Attachment H - Housing Unit and Group Quarters Unit Screening Questions

Attachment I - Question and Answer Brochure

Attachment J - Example of NSDUH Highlights

Attachment K - Example of NSDUH Newspaper Clippings

Attachment L - Showcard Booklet

Attachment M - Quality Control Letter

Attachment N - Sample Design

Attachment O - Interview Payment Receipt

Attachment P - Certificate of Participation

Attachment Q - Unable to Contact Letters

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Attachment T - Follow-up Study Description

Attachment U - Introduction to Clinical Follow-up Interview

Attachment V - Follow-up SCID Interview Content

Attachment W - Follow-up Interview Payment Receipt

Attachment X - December 6, 2006 Mental Health Data Meeting Summary

Attachment Y - NSDUH Confidentiality Pledge

Attachment Z - Response to Federal Register Notice

Attachment AA - CIPSEA Cognitive Interviewing Final Report