

**OMB Submission
National Survey on Drug Use and Health
2007 CIPSEA Materials Study**

National Survey on Drug Use and Health: 2007 CIPSEA Materials Study

SUPPORTING STATEMENT

1. Purpose and Use of Information

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 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.

This package is submitted under the NSDUH Methodological Field Tests generic OMB clearance (OMB No. 0930-0261).

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. Prior to implementation, qualitative cognitive interview data from 24 participants will be analyzed and reported on to evaluate how well potential NSDUH respondents understand the materials, whether they 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.

2. Use of Information Technology

Data will be collected in a face-to-face interview setting. Information will be recorded by the interviewer via paper and pencil. The sessions will be audiotaped so the interviewer can reference the recordings when refining his/her notes. The sessions will involve showing participants a short 2-minute video of a typical interaction between an interviewer and a potential

respondent. This video clip will be taken from the 2007 NSDUH training materials.

3. Efforts to Identify Duplication

The OAS, SAMHSA, is in contact with all major Federal health survey managers and is aware of no other efforts to assess how potential respondents may react to changes made to study participant materials for purposes of CIPSEA, similar to those used in the NSDUH. To date, no duplication of effort has been identified.

4. Consequences if Information Collected Less Frequently

The timetable for finalizing the study participant materials for the 2008 NSDUH dictates the project be completed by August, 2007. This project will not be repeated.

5. Consultation Outside the Agency

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 James Scanlon, Director, Division of Data Policy, Office of Science Policy, ASPE, (202) 690-7100.

There are no unresolved issues resulting from these consultations.

6. Payment to Respondents

Participants will be paid \$50 in the form of a debit card made out to "RTI Respondent" for the one-hour session. This amount is consistent with industry standards for one-hour cognitive interviews, and should be enough to compensate for the respondent's time and any travel expenses incurred (Willis, 2005).

The payment for the interview is mentioned in the following materials: Recruitment Flyers [Attachment A], Recruitment Scripts [Attachment B], Parental Informed Consent Form [Attachment C], Participant Informed Consent Forms [Attachment D], Protocols for Cognitive Interviews [Attachment E], and Receipt for Participation [Attachment F].

7. Methods to Maintain Confidentiality

Concern for the confidentiality and protection of respondents' rights has always played a central part in the implementation of the NSDUH and will continue to be given emphasis.

The CIPSEA Materials Study will incorporate several procedures to ensure that respondents' rights will be protected. The recruitment flyers [Attachment A] will advertise to the participants that "Confidentiality is guaranteed". Also, the recruitment scripts [Attachment B], parental informed consent form [Attachment C], and the participant informed consent forms [Attachment D] all indicate to the participants that the interview will be conducted in private to ensure nobody else overhears their answers; all of their answers will be kept private and confidential; information given by the participants will not be shared with any persons outside the project staff; their name will never be connected with the answers they provide; and that federal law (CIPSEA) requires that their answers be kept confidential and used only for statistical purposes. In these same study materials, participants are informed that their responses are voluntary and are assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular question.

During the recruitment process, potential participants are told that we would like to audiotape the interactions between them and the interviewer during the cognitive interview so we can make sure we have all of the information from them on how our revised materials work. They are told that the audiotapes will be heard only by members of the research team and that having their interview audiotaped is voluntary so they can decline (see the recruitment scripts, [Attachment B]). Additional information on the audiotapes is provided in the parental informed consent form [Attachment C] and the participant informed consent forms [Attachment D]. These documents inform the participants that the audiotape will be transferred to a CD, which will be protected by a password, to protect their privacy. We will store the CDs and tapes in a locked cabinet until the password on the CD expires (within 4 weeks after the last cognitive interview is completed). At that time both the CDs and tapes will be destroyed.

All internal communication regarding a participant will only include the first name of the participant and time of interview. An example of internal communication would be when the recruiter notifies the interviewer of a scheduled appointment with a participant. Any other materials (including the

recruitment screeners, “will call” list, and informed consent forms) connecting the first name of the participant with his/her last name, telephone number, etc. will be locked in a cabinet (if in hardcopy form) or password protected (if in electronic form). This password will be set to expire within 4 weeks after the last cognitive interview is completed and both the electronic files and hardcopies will be destroyed at that time.

Although some personal information will be collected during the recruitment process and the cognitive interviews, data will not be retrieved by personal identifiers, and thus the Privacy Act does not apply to these activities. More specifically, during the recruitment process, we will collect the age, phone number, and city of residence of potential participants who are either aged 12 to 17 or parents of 12 to 17 year olds. Other potential participants aged 18 or older will also be asked about their illegal drug use within their lifetime, the past year, and the past 30 days as well as their level of education. The telephone numbers collected will be used to either remind the participants about their upcoming appointments or to recruit additional participants who were placed on a “will call” list in the event that spaces opened up for them to be interviewed. For potential participants aged 12 to 17, the telephone number will also be used to verify with Directory Assistance that their parents are who they say they are. During the cognitive interviews, we will collect the age, gender, education, race, and Hispanic origin of all participants so analyses for the cognitive interview report can be aggregated according to characteristics of the target population which SAMHSA is trying to reach for the NSDUH that were not required for the recruiting process. No links to individuals will be preserved in the cognitive interview report.

8. Questions of a Sensitive Nature

This study will require the inclusion of people who match selected characteristics of the target population which SAMHSA is trying to reach for the NSDUH, including geography, age, drug use and education. More specifically, the cognitive interviews will be conducted in two different geographical locations (Research Triangle Park, NC and Washington DC) and the initial screening questionnaire used for recruiting [Attachment B] will ask all potential participants, including adolescents, parents or legal guardians of adolescents, and other adults, for their age. For adults aged 18 or older who are responding to the ad for ‘Adults’ and not the ad for ‘Parents or Legal Guardians of Adolescents’ the initial screening questionnaire used for recruiting will ask about drug use and education.

During the cognitive interview [Attachment E], the participants are asked to read through two different versions of the materials used to contact participants of the NSDUH, including the lead letter, survey description, and question and answer brochure [see Attachments G, H, and I respectively for the current versions of these materials and Attachments J, K, and L for the revised versions of these materials]. After the participants read through each version they are asked questions about their perceptions on whether they would agree to respond to the NSDUH survey and if so, would they report honestly to the questions about drug use and mental health within the survey. However, these questions are not considered overly sensitive since they will merely ask the participants about their perceptions of the study participant materials and not about their actual drug use or mental health.

Also, at the end of the cognitive interview, there are questions that ask for each participant's age, gender, education, race, and Hispanic origin. These have been included so analyses for the cognitive interview report can be aggregated according to characteristics of the target population which SAMHSA is trying to reach for the NSDUH that were not required for the recruiting process.

As noted in Section 7 potential participants and the resulting participants will be assured at all stages of the recruiting and interviewing process that the information they provide is voluntary and will be handled in a confidential manner. These efforts will be made to help participants feel more comfortable with the interview situation and more at ease with the interviewer.

Raw data from the screening questionnaires, paper cognitive interviewing questionnaires, and audio tapes that include sensitive information will be stored in locked cabinets (if in hardcopy form) or password protected (if in electronic form) during the recruiting and interview process. None of this information will be retained once the data has been extracted and aggregated; nor will the information become part of a system of records containing permanent identifiers that can be used for retrieval.

9. Estimates of Annualized Hour Burden

Twenty-four participants will be interviewed in this study. It is expected that 144 screenings with potential participants will be completed to obtain the 24 study participants.

Administration of the screening questionnaire during the recruitment process

will take an average of 5 minutes per potential participants. The length of each cognitive interview will vary depending on whether the participant is recruited as an adolescent, a parent or legal guardian of an adolescent, or an adult in general. Since adolescents are unlikely to see the lead letter when it is distributed for the NSDUH, these participants will not be required to read the two versions of this letter during the cognitive interview and as a result will be asked two less questions. Thus, the adolescent interviews are estimated to be about 2-5 minutes shorter than the general adult interviews. On the other hand, participants who are parents or legal guardians of an adolescent will be asked three additional questions about their reactions to the materials concerning recruitment of their child. Thus, the interviews for parents or legal guardians of adolescents are estimated to be about 2-5 minutes longer than the general adult interviews. Based on this information, it is estimated that the average amount of time required to conduct each cognitive interview will be approximately 60 minutes.

Both the recruitment and cognitive interviewing phases of this study will span for approximately three weeks over the months of June and/or July. The recruitment phase will begin one week prior to the cognitive interviews.

The respondent burden for this study is shown in the following table. The hourly wage of \$13.99 was calculated based on weighted data from the 2005 NSDUH respondents' personal annual income.

Estimated Burden for NSDUH CIPSEA Materials Study

Activity	Number of Respondents	Responses per Respondent	Average Burden per Response	Total Burden (Hrs.)	Hourly Wage Rate	Total Hour Cost
Screening	144	1	0.083 hr.	12	\$13.99	\$167.88
Cognitive Interviews	24	1	1.0 hr.	24	\$13.99	\$335.76
TOTAL	144	-	-	36	-	\$503.64

10. Estimates of Annualized Cost to the Government

Total costs associated with the CIPSEA Materials Study are estimated to be \$59,350 over a 12-month performance period. Of the total costs, \$52,900 is for study design, preparation of materials for laboratory testing, recruiting,

conducting the cognitive interviews, analysis and report/publication writing, and approximately \$6,450 represents SAMHSA costs to manage/administrate the survey.

11. Time Schedule, Publication and Analysis Plans

The CIPSEA Materials Study results will be used to gauge the impact of wording changes required for the 2008 NSDUH survey. The sample size and design do not allow for statistical inference to be conducted, and therefore, the analyses will be observational and anecdotal. Debriefings with the cognitive interviewers will be conducted to learn from their experiences about respondents’ reactions to the new wording in the study participant materials.

When the study has been completed, the SAMHSA and RTI liaisons will discuss opportunities for presenting results of the study to the external research community at a professional conference and/or via external publication.

The time schedule for the CIPSEA Materials Study is included below.

2007 NSDUH CIPSEA MATERIALS STUDY SCHEDULE

<u>ACTIVITY</u>	<u>TIME FRAME</u>
Study design and approval	December 2007 to March 2007
Development, review, and approval of cognitive testing materials	April 2007 to June 2007
Recruitment of cognitive interviews	June 2007 to July 2007
Conduct cognitive interviews	June 2007 to July 2007
Analysis and report writing of cognitive interview data	July 2007 to August 2007

12. Respondent Universe and Sampling Methods

The sample of 24 participants to be recruited is non-probability based. It will consist of volunteers who are screened and determined to meet recruitment criteria. Volunteers will primarily be recruited from advertisements posted in

the classified sections of newspapers and/or internet sites. Volunteers will also be recruited via word of mouth and through flyers posted in areas accessible by the general public and containing community bulletin boards such as shopping districts, malls, and restaurants.

The above mentioned objectives require the study to include people who match selected characteristics of the target population SAMHSA is trying to reach for the NSDUH, including geography, age, drug use and education. Details regarding the composition of potential participants for the cognitive interviews are as follows:

- 12 interviews will be conducted in each of the RTI offices in Research Triangle Park (RTP), NC and Washington DC to assess geographical differences.
- To assess differences among the main age groups used in analyses of NSDUH data, participants will be recruited for the following age groups; 12 to 17, 18 to 49, and 50 or older.
- Adolescents require the permission of their parent or legal guardian to participate in the NSDUH study. Thus, parents or legal guardians of persons aged 12 to 17 will be recruited for this study to understand their reactions to the materials concerning recruitment of their children.
- One of the main focuses of the NSDUH is to gather national data on the use of illicit substances. Perceptions of the above mentioned objectives may differ among persons who have never used illegal drugs and persons who have, in particular more current illicit drug users. To alleviate burden of adolescents, the drug use versus non-drug use criterion will only be utilized while recruiting the adult population.
- Understanding and perceptions of the study materials may differ among adults with differing educations. Thus, adults will also be recruited based on whether they received a high school degree (including a GED) or not.
- The majority of the NSDUH interviews are conducted in English. Thus we will focus our efforts on the English speaking population for all of our cognitive interviews.

Exhibit 1 below details the estimated number of participants to be recruited according to the characteristics detailed above for the cognitive interviews. If

after 144 screenings (see Section 9), some of the cells specified in the table are unfilled, potential participants who gave permission to be put on a “will call” list (because the requisite number of participants for their criteria had already been recruited) will be re-contacted to fill the vacant interview slots to maximize the attempt to obtain 24 study participants.

Exhibit 1 – Recruiting Matrix

Site	Characteristics	Estimated Number of Participants
RTP, NC	Aged 12-17	2
RTP, NC	Parents of Persons Aged 12-17	2
RTP, NC	Aged 18-49, illegal drug user in past 12 months, less than high school education	1
RTP, NC	Aged 18-49, illegal drug user in past 12 months, at least high school education	1
RTP, NC	Aged 18-49, never used illegal drugs in lifetime, less than high school education	1
RTP, NC	Aged 18-49, never used illegal drugs in lifetime, at least high school education	1
RTP, NC	Aged 50+, illegal drug user in past 12 months, less than high school education	1
RTP, NC	Aged 50+, illegal drug user in past 12 months, at least high school education	1
RTP, NC	Aged 50+, never used illegal drugs in lifetime, less than high school education	1
RTP, NC	Aged 50+, never used illegal drugs in lifetime, at least high school education	1
Washington DC	Aged 12-17	2
Washington DC	Parents of Persons Aged 12-17	2
Washington DC	Aged 18-49, illegal drug user in past 12 months, less than high school education	1
Washington DC	Aged 18-49, illegal drug user in past 12 months, at least high school education	1
Washington DC	Aged 18-49, never used illegal drugs in lifetime, less than high school education	1
Washington DC	Aged 18-49, never used illegal drugs in lifetime, at least high school education	1
Washington DC	Aged 50+, illegal drug user in past 12 months, less than high school education	1
Washington DC	Aged 50+, illegal drug user in past 12 months, at least high school education	1

Washington DC	Aged 50+, never used illegal drugs in lifetime, less than high school education	1
Washington DC	Aged 50+, never used illegal drugs in lifetime, at least high school education	1

13. **Information Collection Procedures**

Up to 24 participants will be recruited from advertisements posted in the classified sections of newspapers or on internet sites. Volunteers will also be recruited via word of mouth and through flyers posted in areas accessible by the general public and containing community bulletin boards such as shopping districts, malls, and restaurants. [See Attachment A for recruitment flyers]. Potential participants who call into the study line will be screened for eligibility [Attachment B]. Adolescents who call in will be screened for their geographical location and age, and will require permission from their parent or legal guardian before being recruited. Parents or legal guardians will be recruited in one of two ways; via the persons aged 12 to 17 who call in to participate in the study [Attachment B – Screener for Adolescents] and as parents or legal guardians of persons aged 12 to 17 in general [Attachment B – Screener for Adults]. Screening questions will ask potential participants aged 18 or older (excluding those being screened as parents or legal guardians of persons aged 12 to 17) for their highest level of education completed and whether they have ever, in the past 12 months, or in the past 30 days used the following illegal drugs; marijuana, cocaine, crack, heroin, hallucinogens (including LSD, PCP, and ecstasy), and illegal forms of methamphetamine. Eligible respondents will be scheduled for a one hour cognitive interview.

Potential participants who call the RTI study line after the requisite number of participants has been recruited will be placed on a “will call” list with their permission, but only for the duration of the interviewing phase. During this phase, individuals on the “will call” list may be called to ask if they are available, should one or more originally scheduled participants not arrive for a scheduled interview. As specified in Section 7, recruitment and contact information will be kept in locked cabinets and via password protected electronic files and not shared except with those who are assigned to complete the interviews.

When each participant arrives for their interview, they will be greeted and asked to listen to instructions and information from the interviewer, including the signing of a confidentiality form [Attachment D]. All cognitive interviews will be audiotaped upon consent of each participant and a subset in Washington DC

will be observed by SAMHSA staff from a separate room, again upon consent of each participant. Participants will have the right to decline to be audiotaped or observed without being excluded from participation.

During the interview, participants will first be asked to read through one version of the study materials, including a lead letter, study description, and question and answer brochure. Then the participants will be read the NSDUH Introduction and Informed Consent for Interview and then shown a short 2-minute video of a typical interaction between an interviewer and a potential respondent. The interviewer will then ask the participants pre-scripted questions based on the materials they have just read and heard and the video they saw. Then the participants will be asked to read through a second version of the study materials. The NSDUH Introduction and Informed Consent for Interview will be repeated to the participant. The interviewer will then ask the participants pre-scripted questions based only on the second set of materials they read and heard. Then the interviewer will ask the participants pre-scripted questions comparing the two different versions of the materials. Finally, the interviewer will ask the participants pre-scripted questions about their general understanding of various terms and phrases in the materials the participants read earlier. All pre-scripted probes are found in the cognitive interviewing protocols in Attachment E. However, the interviewer requires the latitude to deviate from and/or make changes to these protocols “on the fly” during the interviewing process in order to follow up on new information that is gained from respondents during the course of the interviews. After the interview, participants will be thanked, paid for their time with a \$50 gift card, and will be asked to sign a participation receipt form [Attachment F].

Since adolescents are unlikely to see the lead letter in the main NSDUH survey, the lead letter will not be included in the study materials they are asked to read.

The two versions of the study materials are the version used in the 2007 NSDUH and the newly revised version incorporating the CIPSEA language. All participants will see both versions during their interview. However, the order in which they receive the materials will be randomly assigned. See Attachments G, H, and I respectively for the current versions of the study materials (lead letter, study description, and question and answer brochure) and Attachments J, K, and L respectively for the revised versions of these materials

14. Methods to Maximize Response Rates

To assure the participation of the recruited cognitive interviewing participants,

each selected person will receive a reminder telephone call the day before the interview with directions to the facility and an opportunity to ask any questions about the purpose or logistics of the study. The \$50 incentive will also help assure participation.

15. Tests of Procedures

The activities to be conducted under this approval are in themselves tests of procedures.

16. Statistical Consultants

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ATTACHMENTS

- Attachment A - Recruitment Flyers
- Attachment B - Recruitment Scripts
- Attachment C - Parental Informed Consent Form
- Attachment D - Participant Informed Consent Forms
- Attachment E - Protocols for Cognitive Interviews
- Attachment F - Receipt for Participation
- Attachment G - Lead Letter (Current Version)
- Attachment H - Study Description (Current Version)
- Attachment I - Q&A Brochure (Current Version)
- Attachment J - Lead Letter (Revised Version)
- Attachment K - Study Description (Revised Version)
- Attachment L - Q&A Brochure (Revised Version)

REFERENCES

Willis, G. B. (2005). *Cognitive Interviewing: A Tool for Improving Questionnaire Design* (p. 144). Sage Publications, Inc.: Thousand Oaks, CA.