OMB Submission

National Survey on Drug Use and Health
Cognitive Interviews for Prescription Drug Module Redesign

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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, noninstitutionalized population aged 12 or older. The conduct of NSDUH is paramount in meeting a critical objective of SAMHSA's mission to maintain current data on the prevalence of substance use in the United States.

This package is submitted under the NSDUH Methodological Field Tests generic OMB clearance (OMB No. 0930-0290).

The 2009 NSDUH indicated that the nonmedical use (or misuse) of prescription psychotherapeutic drugs (pain relievers, tranquilizers, stimulants, and sedatives) was second only to marijuana in prevalence for substances other than tobacco and alcohol. Furthermore, the number and percentage of past month nonmedical users of psychotherapeutic drugs in 2009 (7.0 million or 2.8 percent) were higher than in 2008 (6.2 million or 2.5 percent) (Office of Applied Studies [OAS], 2010). However, the last major redesign of the prescription drug questions in NSDUH occurred more than a decade ago in preparation for the 1999 survey. Several of the prescription drugs currently included in NSDUH—particularly for stimulants and sedatives—have been discontinued or are no longer legally available by prescription in the United States. New prescription drugs or new formulations also have been approved since the last major redesign, but the survey questions that are used for publishing estimates on the prevalence of prescription drug misuse do not explicitly include these newer drugs. Boyd and McCabe (2008) noted limitations of the current questions on the nonmedical use of prescription drugs in NSDUH, the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), and the Monitoring the Future (MTF) study; they advocated for the disaggregation of the different components of nonmedical use to broaden the understanding of the types of nonmedical users and their associated health risks and to assist in the development of more targeted prevention messages. It has become evident that questions about more recent misuse of specific prescription drugs (e.g., in the past 12 months) also are more relevant to NSDUH data users than are the current NSDUH questions about lifetime misuse. Therefore, a comprehensive redesign of the prescription drug questions in NSDUH is critical for ensuring that the survey continues to collect the most relevant data for policymakers and public health planners.

The questions to be tested have been subjected to expert review, and the criteria for defining nonmedical use have been identified for testing. Work also has been completed on recommendations for existing prescription drugs to delete from the instrument and other prescription drugs to add to the survey. The Center for Behavioral Health Statistics and Quality (CBHSQ, formerly known as OAS) within SAMHSA submitted these

recommendations for review by experts on issues related to the nonmedical use of prescription drugs (Section 5). Findings from this work also were presented on November 9, 2009, at the American Public Health Association (APHA) Annual Meeting in Philadelphia, PA (Kroutil, Colliver, & Gfroerer, 2009).

The next step in this study is to evaluate the new question wording that has been developed to describe nonmedical use of pain relievers and stimulants. The current NSDUH questions ask about lifetime use of specific prescription drugs "that were not prescribed for you or that you took only for the experience or feeling they caused"; these questions are self-administered. With the current NSDUH questions, respondents must mentally process at least two pieces of information in order to answer each question: (a) Have they used the specific prescription drug(s) in the question for any reason? and (b) If so, have they used it (or them) in any of the ways indicated in the question? The revised questions to be tested will focus on the nonmedical use of prescription pain relievers and stimulants within the past 12 months rather than in the lifetime period. In contrast to the current question wording, the revised instrument also will split these cognitive tasks into two separate sets of questions.

Respondents in the current NSDUH interview are instructed to request printed "pill cards" from the interviewers when they reach the prescription drug questions; the pill cards are designed to aid respondents in identifying specific prescription drugs they misused and in recalling their misuse of the categories of prescription pain relievers, tranquilizers, stimulants, or sedatives as a whole. The printing of these pill cards is an expense that NSDUH incurs every year. However, respondents do not always ask the interviewer for the pill cards when they get to that point in the interview or look at the pill cards for all four categories of prescription drugs in NSDUH. Therefore, another important aspect of the revisions to the prescription drug questions in NSDUH is to test a more extensive use of electronic images of prescription drugs that are displayed on the laptop computer screen. On-screen electronic images of prescription drugs have been used successfully in NSDUH, but only for two medications in a supplemental section of the interview.

In addition, once the iterative cognitive testing has helped evaluate and determine the final question wording, the redesigned NSDUH instrument and methods need to be tested with a broader population prior to inclusion in the main annual survey. In particular, CBHSQ plans to conduct a field test of the redesigned questionnaire (including, but not limited to, redesigned prescription drug questions and new health questions) and a "dress rehearsal" of a comprehensive set of redesigned survey procedures. Therefore, a section on other health issues has been included for cognitive interviewing along with plans for the testing of the revised prescription drug questions. In addition, the questions about nonmedical use of prescription drugs will be preceded by questions about use of tobacco, alcohol, and illegal drugs to evaluate respondent understanding of the new prescription drug questions in the context of questions about use of other substances.

Cognitive interviews will be conducted with 40 participants across three rounds of interviews (16 in Round 1 and 12 each in Rounds 2 and 3). Qualitative interview data from these participants will be analyzed to evaluate how well potential NSDUH respondents understand the concept and language of the questions, whether they find them difficult to answer, whether they find any questions to be too sensitive, and whether they are able to provide accurate reports of their nonmedical use of prescription drugs and other health issues.

2. Use of Information Technology

Data will be collected in a face-to-face interview setting. Information will be collected electronically via computer-assisted interviewing (CAI) on a laptop computer. The interview will focus on questions related to the nonmedical use of prescription drugs, health care utilization, and other health issues. In Rounds 1 and 2, the interviewer will administer a few demographic questions and then participants will be asked to read and answer the remaining questions aloud and discuss them with the interviewer. If necessary, changes will be made to the question wording after each round. In Round 3, the questions will be administered using audio computer-assisted self interviewing (ACASI) for the majority of the interview, with participants responding to interviewer probes after hearing the question read to them. The cognitive interview sessions in all rounds will be audio recorded so the interviewer can reference the recording when refining his or her notes.

3. Efforts to Identify Duplication

CBHSQ 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 the NSDUH prescription drug questions. To date, no duplication of effort has been identified.

4. Consequences if Information Collected Less Frequently

The timetable for finalizing the survey instrument for field testing is dependent on completion of the cognitive interviewing and the reporting of the results for this study. Thus, collection of the relevant information based on a schedule that would extend this study past the target completion date of October 31, 2011, will affect the schedule for field testing a revised survey instrument and for implementing an overall redesign. This project will not be repeated.

5. Consultation Outside the Agency

A number of experts on prescription drug issues have provided consultation on key issues related to the redesign of the prescription drug questions in NSDUH and recommendations for prescription drugs to add to or delete from the survey. CBHSQ requested and received input on key issues related to the redesign, including (a) how to operationalize nonmedical use in NSDUH questions; (b) the therapeutic categories of prescription drugs to be covered in NSDUH; (c) the period of use to focus on for specific drugs; and (d) tracking trends in nonmedical use of prescription drugs, given the dynamic nature of the prescription drug market. Table 1 lists the names and contact information for these experts.

There are no unresolved issues resulting from these consultations.

Table 1. Experts Consulted about Prescription Drug Redesign Issues for NSDUH

University-Based Researchers

Name	Affiliation	Contact Information
Nathaniel Katz, M.D.[1]	Tufts University School of Medicine	nkatz@analgesicresearch.com
Sean Esteban McCabe, Ph.D.[1]	University of Michigan	plius@umich.edu
Patrick O'Malley, Ph.D.[1]	Institute for Social Research University of Michigan Monitoring the Future Study	pomalley@umich.edu
Linda Simoni-Wastila, Ph.D[1]	School of Pharmacy University of Maryland	lsimoniw@rx.umaryland.edu
James P. Zacny, M.D.[2]	Department of Anesthesia and Critical Care University of Chicago	jzacny@dacc.uchicago.edu
Key Personnel in Related Government Agencies		
Name	**Affiliation**	**Contact Information**
Wilson M. Compton, M.D.[1]	National Institute on Drug Abuse	wilson.compton@nih.gov
Michael Klein, Ph.D.[1]	Food and Drug Administration	Michael.Klein@fda.hhs.gov
Marsha Lopez, Ph.D.[1]	National Institute on Drug Abuse	lopezmar@nida.nih.gov
Nicholas Reuter[1]	Center for Substance Abuse Treatment, SAMHSA	Nicholas.Reuter@samhsa.hhs.gov
Gamaliel Rose, M.B.A[3]	Drug Enforcement Administration	Gamaliel.S.Rose@usdoj.gov

[1] Provided consultation about overall redesign issues and specific prescription drug content.
[2] Provided consultation about overall redesign issues.
[3] Provided consultation about specific prescription drug content.

6. Payment to Respondents

Participants aged 18 or older will be given $40 in the form of a Visa® gift card and those aged 12 to 17 will be given $30 in the form of a Visa® gift card. Adolescents are being offered a lower incentive at the request of OMB. The youth respondents, however, will be completing the same task as the adult. These Visa® gift cards will be made out to "RTI Respondent." This amount should be sufficient to compensate for the participants' time and any travel expenses incurred, but may not be sufficient to encourage participation (Willis, 2005). Our past experience with other cognitive interviews indicates that offering an adequate incentive is important for recruiting substance users for 60-minute cognitive interviews, particularly in higher cost-of-living areas such as Washington, DC. Given the relationship of the schedule for cognitive interviewing to the schedule for field testing, a dress rehearsal, and the plans for fielding the revised NSDUH instrument, a higher incentive may be required if there are significant delays in recruiting participants. This is especially true of the youth drug users since they are historically more difficult to recruit and are being offered the lower incentive. Should this occur, SAMHSA will supply OMB with documentation of recruiting rates and petition for an increase in the incentive.

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

7. Methods to Maintain Confidentiality

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

The Cognitive Interviews for Prescription Drug Module Redesign will incorporate several procedures to ensure that respondents' rights will be protected. The recruitment flyers [Attachment A] will advertise to the participants that "All responses will be kept confidential under federal law." Also, the recruitment screening scripts [Attachment B], parental permission form [Attachment D], and the participant informed consent forms [Attachment E] all indicate to the participants that the interview will be conducted in private to ensure that no one else will overhear 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 (i.e., the Confidential Information Protection and Statistical Efficiency Act, or 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 will be told that we would like to audio record the interactions between them and the interviewer during the cognitive interview to help ensure that we capture all pertinent information on how our new questions work. They also will be told that the audio recordings will be heard only by members of the research team and that their decision to have the interview audio recorded is voluntary; thus, they can decline (see the recruitment screening scripts [Attachment B]). In addition, some respondents (and parents or guardians) may be asked to give permission for an RTI or SAMHSA staff member to observe the interview from a separate room. Either the participant or the parent or guardian of an adolescent can decline to have the interview observed. Observers will not be present at every interview and this process is also voluntary, so declining to be observed will not affect the participant's eligibility for the study. Additional information on the audio recordings and observation process is provided in the Parental Permission Form [Attachment D] and the Participant Informed Consent Forms [Attachment E].

Cognitive interview sessions will be recorded using a handheld electronic MP3 recorder. The recordings will be named numerically so that they cannot be readily connected back to a particular participant. The links between the numeric filenames and participant identities will be kept separately from the audio recordings at all times. The MP3 recorder will remain in the possession of the cognitive interviewer or in a locked storage cabinet at all times. The MP3 files also will be uploaded to a secure computer network storage location and deleted from the recording device. Recordings will be destroyed within 60 days of the end of this study.

All internal communication regarding a participant will include only the first name of the participant and the 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 or her last name, telephone number, and so on will be locked in a cabinet (if in hard-copy form) or password protected

(if in electronic form). This password will be set to expire 4 weeks after the last cognitive interview is completed, and both the electronic files and hard copies 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. Thus, the Privacy Act does not apply to these activities. More specifically, during the recruitment process, the RTI recruiter will collect the age, phone number, city of residence, any significant physical limitations that would preclude participation, participation in other research studies, and prescription drug use in the past 12 months. 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 also will be used to attempt to verify through Directory Assistance that their parents are who they say they are [see Attachment B].

As a further protection, interviewers will sign the consent/assent forms [Attachment E] so that these forms do not record participants' names. As shown in Attachment D, however, a parent or legal guardian will need to sign the Parental Permission Form as documentation that permission has been given for a recruited adolescent to participate. Nevertheless, the additional methods described in this section for maintaining confidentiality will continue to apply for protecting adolescents' identities. During the cognitive interviews, we will collect the age and gender of all participants, but only to inform the CAI program as to which questions to display and to tailor wording. Cognitive interview participants also will be periodically reminded not to mention anything during the interview that could identify themselves or another person. No links to individuals will be preserved in the cognitive interview report.

8. Questions of a Sensitive Nature

There are questions of a sensitive nature. The questions to be tested deal principally with the nonmedical use of prescription pain relievers and stimulants in the past 30 days and past 12 months. Other questions, such as those on pregnancy, HIV/AIDS, and alcohol use by persons under the age of 21, could also be considered sensitive, but will not be the main focus of this study. To thoroughly test the prescription drug questions in particular, the target population for the cognitive interviews will need to include adults and adolescents who have used prescription pain relievers or stimulants in the past 12 months for any reason (including prescribed use for a medical problem) and those who have misused these prescription drugs. Inclusion of participants who have taken prescription pain relievers or stimulants that they were prescribed is important for testing participants' ability to answer the questions correctly; for example, participants with prescriptions of their own who have used these medications as prescribed and for the reason they were prescribed them should (in principle) not endorse questions indicating "nonmedical" use. The initial screening questionnaire used for recruiting [Attachment B] will ask all potential participants, including adolescents and adults, for their age and whether they have used any prescription pain relievers and stimulants in the past 12 months.

During the cognitive interview, the participants will be instructed on how to employ "think-aloud" techniques when answering the questions that have been added to the instrument. The interviewer will use a set of scripted probes to best understand how the participants understand each question and how features of the question affect responses.

As noted in Section 7, potential participants and the actual 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 protocols, and audio recordings that include sensitive information will be stored in locked cabinets (if in hard-copy form) or password protected (if in electronic form) during the recruiting and interview process. None of this information will be retained once the data have 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

Forty participants will be interviewed in this study. It is expected that approximately 240 screenings with potential participants will be completed to obtain the 40 study participants.

Administration of the screening questionnaire during the recruitment process will take an average of eight minutes per participant. The estimated average amount of time required to conduct each cognitive interview will be approximately 60 minutes. As necessary, however, the interviewer will conclude the interview so that the informed consent procedures, administration of the interview, and administration of the incentive can be completed in no more than 90 minutes.

Both the recruitment and cognitive interviewing phases for all three rounds of interviews for this study will approximately span the months of December 2010 through September 2011. The recruitment phase will begin a few days prior to the start of cognitive interviewing.

The respondent burden for this study is shown in Table 2. The hourly wage of $14.71 was calculated based on weighted data from the 2009 NSDUH respondents' personal annual income.

Table 2. Estimated Burden for Cognitive Interviews for Prescription Drug Module Redesign

Activity	Number of Respondents	Responses per Respondent	Average Burden per Response	Total Burden (Hours)	Hourly Wage Rate	Total Hour Cost
Screening	240	1	0.133 hour	31.92	$14.71	$469.54
Cognitive Interviews	40	1	1 hour	40.00	$14.71	$588.40
TOTAL	240	–	–	71.92	–	$1,057.94

10. Estimates of Annualized Cost to the Government

Total costs associated with the cognitive interviews for the NSDUH Prescription Drug Module Redesign are estimated to be $441,506 over a 12-month performance period. Of the total costs, $379,411 is for study design, preparation of materials for laboratory testing, recruiting, conducting the cognitive interviews, analysis, and report/publication writing; approximately $62,095 represents SAMHSA's costs to manage and administrate the survey.

11. Time Schedule, Publication, and Analysis Plans

The results of the cognitive interviews for the NSDUH Prescription Drug Module Redesign will be used to gauge the impact of wording changes and question additions that are being considered for the redesigned NSDUH questionnaire. The sample size and design do not allow for statistical inference to be conducted; therefore, the analyses will be observational and anecdotal. Debriefings with the cognitive interviewers will be conducted to learn from their experiences about participants' reactions and responses to the survey questions and interviewer probes. The results will be summarized in a brief report and used to make recommendations for questions to be included in a questionnaire field test.

The time schedule for the cognitive interviews for the NSDUH Prescription Drug Module Redesign is included in Table 3.

Table 3. Schedule for Cognitive Interviews for Prescription Drug Module Redesign

Subtask	Due Date
Recruiting for cognitive interviews begins	December 13, 2010
Round 1 cognitive interviews begin	December 20, 2010
Round 2 cognitive interviews begin	March 31, 2011
Round 3 cognitive interviews begin	August 2, 2011
All cognitive interviews completed	September 1, 2011
Final cognitive interview report completed	October 31, 2011

12. Respondent Universe and Sampling Methods

The sample of 40 participants to be recruited will not be probability based. It will consist of volunteers who are screened and determined to meet recruitment criteria. Table 4 shows the sample targets for each round of cognitive interviewing.

Participants will be recruited from advertisements posted at outpatient drug treatment centers in the relevant geographic areas and from the classified sections of Internet sites. If these methods fail to produce adequate numbers, RTI will place newspaper ads or distribute flyers in other locations (e.g., medical clinics, student unions) after having received appropriate permissions. No participants from substance abuse treatment programs are targeted for the third round of cognitive interviews. However, individuals from treatment programs who responded to the recruitment in Round 2 but were placed on a waiting list could still be eligible to be interviewed in Round 3.

Table 4. Targeted Sample Sizes per Cognitive Interview Round, by Location, Age Group, and Recruitment Source

	Cognitive Interview Round			
Group/Recruitment Source	**Round 1**	**Round 2**	**Round 3**	**Total**
Location	16	12	12	40
Research Triangle Park, NC	6	4	4	14
Washington, DC	5	4	4	13
Chicago, IL	5	4	4	13
Adults Aged 18 or Older	16	5	7	28
General Population	8	3	7	18
Substance Abuse Treatment	8	2	0	10
Youths Aged 12 to 17	0	7	5	12
General Population	0	4	5	9
Substance Abuse Treatment	0	3	0	3
Total	16	12	12	40
General Population	8	7	12	27
Substance Abuse Treatment	8	5	0	13

A total of 13 to 14 interviews across all three rounds will be conducted in each of the following three geographic areas: Research Triangle Park (RTP), NC; Washington, DC; and Chicago, IL. Participants who are recruited from outside of substance abuse treatment programs will be interviewed at RTI offices in these three geographic areas. Participants who

are recruited from outpatient substance abuse treatment programs will be given the option to be interviewed onsite at their programs.

The objectives mentioned previously for the cognitive interviewing require the study to include people who match selected characteristics of the target population that NSDUH is trying to reach. Education level (for adults) also is important for testing participant understanding and interpretations of the questions. The questions must be worded in a way that maximizes the potential for comprehension by people with varying levels of education.

To aid in the timely collection of information on the new questions being tested for measuring nonmedical use in NSDUH, all participants recruited in Round 1 will be aged 18 or older. Information on problems encountered or preferences that adult participants in Round 1 have for a particular wording version will inform decisions about which new question version is tested further with both adults and adolescents in subsequent rounds.

Participants recruited from substance abuse treatment programs in all rounds will be required to have used prescription pain relievers or stimulants in the past 12 months. Table 5 presents additional sample targets by interview round.

The additional targets in Table 5 are not firm sample "quotas" to be applied. Rather, they may be applied or relaxed as needed to allow SAMHSA to obtain the targeted numbers of interviews in each round. If some of the targets in Table 5 have not been met after the screenings have been completed for a given round (see Section 9), sample targets for these characteristics will be relaxed in the following order:

- gender;
- education (for adults);
- age group (for adults); then
- prescription pain reliever or stimulant use in the past 12 months (any use, for participants recruited from outside of substance abuse treatment).

Thus, targets for characteristics closer to the top of the list will be "softer," and those closer to the bottom of the list will be "firmer" targets. Potential participants who have given permission to be put on a "will call" list (because they had characteristics that were already well-represented among those who had already been recruited) will be recontacted to fill the vacant interview slots to maximize the attempt to obtain the targeted number of participants in a given round.

The eligibility requirement of use of prescription pain relievers or stimulants in the past 12 months for participants recruited from outpatient substance abuse treatment programs is designed to include adequate numbers of nonmedical users of these prescription drugs. As

Table 5. Sample Targets for Selected Characteristics, by Cognitive Interview Round

Group	Cognitive Interview Round		
	Round 1	**Round 2**	**Round 3**
Adults Aged 18 or Older	16	5	7
Prescription Drug Use, Past 12 Months[1]			
Any Pain Reliever	At Least 2	At Least 1	At Least 1 for Pain Relievers or Stimulants
Any Stimulant	At Least 2	At Least 1	
Education			
High School Diploma, GED, or Lower	At Least 3	At Least 1	At Least 1
Gender			
Male	At Least 4	At Least 2	At Least 2
Female	At Least 4	At Least 2	At Least 2
Age Group			
18 to 25	At Least 3	At Least 1	At Least 1
50 or Older	At Least 3	At Least 1	At Least 1
Youths Aged 12 to 17	0	7	5
Prescription Drug Use, Past 12 Months[1]			
Any Pain Reliever	--	At Least 1	At Least 1 for Pain Relievers or Stimulants
Any Stimulant	--	At Least 1	
Gender			
Male	--	At Least 2	At Least 2
Female	--	At Least 2	At Least 2

-- = Not applicable.

NOTE: Target groups are not mutually exclusive. For example, an adult aged 50 or older who had a high school diploma, GED, or lower would contribute toward satisfying the targets for both age group and education.

[1] For participants recruited from outside of substance abuse treatment. Based on reports of use of prescription drugs of interest and excluding over-the-counter-drugs.

noted previously, however, nonmedical use of prescription drugs is not an absolute requirement because of the need to test the ability of the new prescription drug questions to allow participants to discriminate between appropriate use of prescription drugs and nonmedical use. In addition, feedback from participants who have not used any prescription pain relievers or stimulants in the past 12 months also will be important for gauging participants' ease in answering the new questions and the clarity of the new questions. Furthermore, the participants who have not used these prescription drugs in the past 12 months may provide important feedback on other health questions.

Because persons who have had recent experience with other survey research may bias the data and conclusions, persons who respond to the recruitment but have participated in more than one prior research study in the past 12 months (regardless of who conducted the study or the content) or in any prior RTI research study in this period will be ineligible for the cognitive interview. Individuals may still be eligible for the cognitive interview if they participated in only one other study in the past 12 months and this study was not focused on survey or social science research (e.g., participation in a clinical drug trial). However, prior research participants in this latter group would be placed on a waiting list and would be called for an interview appointment only if additional participants are needed to meet overall sample targets in a given round or targets for specific subgroups.

Because the cognitive interview procedure will require participants to see the questions on the laptop computer screen (or listen to them in Round 3), persons with physical limitations that would prevent them from seeing the question text or communicating their answers to interviewers will not be eligible.

The majority of the NSDUH interviews are conducted in English. In 2009, for example, more than 96 percent of the final completed interviews were in conducted in English, and fewer than 4 percent were conducted in Spanish. Thus, all of the cognitive interviewing efforts for this study will focus on the English-speaking population.

13. Information Collection Procedures

Up to 28 adult participants and up to 12 adolescent participants will be recruited from advertisements posted in the classified sections of Internet sites and through local outpatient drug treatment centers [see Attachment A for recruitment flyers]. Potential participants who call into the study line will be screened for eligibility [Attachment B]. Potential participants who call in will be screened for their geographical location and age, participation in prior research studies, the presence of any physical limitations that would preclude their effective participation, and use of prescription pain relievers or stimulants in the 12 months prior to the screening interview. When the recruiter determines that a caller in Rounds 2 or 3 is an adolescent, the recruiter will obtain initial permission over the telephone from his or her parent or legal guardian before collecting additional information from the adolescent [see Attachment B]. The parent or legal guardian of the adolescent (rather than the adolescent himself or herself) also will be asked about any physical limitations that the adolescent has. Potential adult participants in each round will be asked this screening question about physical limitations.

If an adolescent is eligible and confirms his or her interest in participating at the conclusion of the screening call, RTI will send two copies of the parental permission form [Attachment D] via Federal Express and schedule a follow-up telephone appointment with the identified parent of the eligible youth; to reduce burden on the parents, they will not need to sign for the letter. The cover letter accompanying the permission form [Attachment C] will remind parents of the appointment time and include additional information about the call. During the telephone appointment, the recruiter will read the parental permission form to the parent, answer any of the parent's questions, and request signed permission from the parent for the adolescent to participate. The parents will sign and return one copy of the permission form and keep the other copy for their records. Once RTI has received a parent's signed permission form (to be returned in a self-addressed envelope included with the cover letter and permission form), the recruiter will coordinate with the parent and adolescent to schedule a cognitive interview appointment with the adolescent. This approach of finalizing an interview appointment with an eligible adolescent following receipt of signed parental permission is intended to reduce the occurrence of nonproductive appointments with adolescents who come to their appointments but cannot be interviewed because RTI has not received their parents' permission forms.

For eligible adults, the recruiter will explain the study further during the screening call and request a verbal indication of the adult's interest in participating. As with adolescents,

eligible adult respondents who affirm their interest will be scheduled for a 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. Callers who have been placed on the will-call list but were not interviewed in a previous round may still be eligible to be called in the next round of cognitive interviews if one or more originally scheduled participants did 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 an interview, he or she will be greeted and asked to listen to instructions and information from the interviewer. Before the interview begins, the participant will be read the Participant Informed Consent. The interviewer will sign a confidentiality form [Attachment E] indicating that consent or assent has been obtained from the participant. All cognitive interviews will be audiotaped upon consent (or assent and parental consent, in the case of adolescents) of each participant, and a subset may be observed by a staff member, again upon the consent or assent of each participant. Participants will have the right to decline to be audiotaped and/or observed without being excluded from participation. The interview will commence after the informed consent process is complete. The interviewer will begin by asking the participant about his or her age and gender (to determine how the CAI program should route the participant through the questions in the interview) and then will show each respondent how to navigate through the CAI program. Participants then will complete a tutorial.

Following the tutorial, participants will be asked a subset of the NSDUH core drug screening questions. These include questions about the use of tobacco products, alcohol, marijuana, cocaine, heroin, methamphetamines, hallucinogens, and inhalants. Some of these screening questions have been reworded and are being presented in a new format for these interviews. However, the substantive measures from the NSDUH core drug screening questions have not changed. Asking participants about use of other drugs in NSDUH before they are asked questions about prescription drugs also will inform the study about how participants interpret and answer questions about the use of prescription drugs in the context of having been asked earlier questions about other substances. Questions about participants' most recent use of alcohol (if they reported lifetime alcohol use) are included to test questions about the nonmedical use of prescription drugs in combination with alcohol in the past 30 days.

In contrast to the current NSDUH questions, which ask about use of specific prescription drugs "that were not prescribed for you or that you took only for the experience or feeling they caused," the revised questions split the cognitive tasks of identifying use of specific prescription drugs and nonmedical use of the prescription drugs that participants reported using into separate sets of questions.

Nonmedical use will be defined as use "in any way a doctor did not direct you to use" prescription pain relievers or stimulants. The following examples of nonmedical use will be presented to participants:

- using it without a prescription of your own;

- using it in greater amounts, more often, or longer than you were told to take it; or
- using it in any other way a doctor did not direct you to use it.

In Round 1, these examples will be presented at the beginning of the question series and will not be repeated. In Round 2, participants will be given the option of pressing a function key to display the examples of nonmedical use again. Offering this recall aid in Round 2 but not Round 1 will allow testing of (a) how well participants remember these examples of nonmedical use in Round 1 without a reminder; (b) whether and how often participants use this recall aid in Round 2; and (c) the point in either round when recall of these examples may begin to decay.

Participants who report nonmedical use of specific prescription pain relievers or stimulants in the past 12 months will be asked more detailed questions about their nonmedical use. Participants will then receive questions about health service utilization and health conditions following any questions they receive about the nonmedical use of prescription pain relievers and stimulants.

As noted previously, all questions will be interviewer-administered in Rounds 1 and 2 of interviewing. In Round 3, the demographic questions will continue to be interviewer-administered, but the remaining questions will be completed via ACASI. For each set of questions, participants will be instructed to read the questions aloud and discuss them with the interviewer. Participants will deliver concurrent verbal reports of their thought process or will provide thoughts on how they are answering the question before the question is answered (Forsyth & Lessler, 1991). Interviewers will be provided with a series of probes and questions that will further explore the quality of the responses and whether these responses are meeting the researchers' goals. Interviewers are instructed to use the probes as a guideline, but are not required to use all of them, be limited by them, or to read them exactly as written (Beatty, 2004). Interviewers may probe based upon the content of the interview and participant responses. All pre-scripted probes are found in the cognitive interviewing protocols [see Attachment F]. After the interview, participants will be thanked, given a Visa® gift card for their time ($40 gift card for adults; $30 gift card for adolescents), and will be given a participation receipt form [Attachment G].

14. Methods to Maximize Response Rates

To ensure 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 interview location and an opportunity to ask any questions about the purpose or logistics of the study. The incentives will also help ensure participation. Prospective participants who were placed on a will-call list at the end of Rounds 1 and 2 may also be recontacted for the next round of interviews to maximize participation.

15. Tests of Procedures

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

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ATTACHMENTS

Attachment A - Cognitive Interview Recruitment Flyers

Attachment B - Cognitive Interview Recruitment Screening Scripts

Attachment C - Cognitive Interview Cover Letter to Parents of Eligible Adolescents

Attachment D - Cognitive Interview Parental Permission Form

Attachment E - Cognitive Interview Participant Informed Consent Forms

Attachment F - Cognitive Interview Instrument and Protocol

Attachment G - Cognitive Interview Receipt for Participation

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