

**OMB Submission  
National Survey on Drug Use and Health  
Cognitive Interviews for Questionnaire  
Redesign**

# National Survey on Drug Use and Health Cognitive Interviews for Questionnaire Redesign

## 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 to maintain current data on the prevalence of substance use in the United States. In order to continue producing current data, SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) must update the NSDUH periodically to reflect changing substance abuse and mental health issues. CBHSQ is planning to redesign the NSDUH for the 2015 survey year. The redesign will seek to achieve three main goals: 1) to bring the NSDUH costs in line with anticipated budget levels, 2) to revise the questionnaire to address changing policy and research data needs, and 3) to modify the survey methodology to improve the quality of estimates and the efficiency of data collection and processing. SAMHSA is requesting approval to conduct 40 cognitive interviews to test revisions to the questionnaire associated with goal #2. This package is submitted under the NSDUH Methodological Field Tests generic OMB clearance (OMB No. 0930-0290).

The objective of the questionnaire revisions is to improve questions that cause known or suspected problems with the current NSDUH questionnaire, as well as to add new content to address current data needs. Revisions will also be designed to reduce errors associated with usability problems in the design and layout of the computer-assisted interviewing (CAI) instrument. The changes include revised prescription drug modules, revised front end demographics, a revised alcohol module, a new methamphetamine module, a revised special drugs module, a revised consumption of alcohol module, and a revised back end demographics section.

Specific changes to the core modules will be tested:

- New items will be added to core demographics, including new military veteran questions.
- Hallucinogen items currently included in Special Drugs for ketamine, tryptamines (DMT, AMT, and "Foxy"), and Salvia divinorum will be moved to the core Hallucinogens module. Updates will be made to the routing of the Hallucinogens module to account for question changes.
- New inhalants questions for markers and air duster will be added.

Changes to the non-core modules that will be tested include:

- New modules for methamphetamine and health care will be added.
- The Special Drugs module questions about needle use will be reworded, and questions about use of methamphetamine and prescription stimulants with a needle will be moved to the corresponding core modules.
- Education, Health Insurance, and Income will all be moved to ACASI portion of the interview. In addition, the top response category for Income will be revised.
- A new module will introduce proxy respondents to the CAI program.

Revised questions for use and nonmedical use of prescription pain relievers and stimulants have been tested with 40 respondents in a previous phase of cognitive interviewing (OMB No. 0930-0290). This previous phase tested updated modules for pain relievers and stimulants that accounted for changes in the availability of new drugs and omitted questions about drugs that are no longer commercially available. This previous phase also tested a new definition of nonmedical use of prescription drugs.

The structure of the questionnaire will be revised to group questions about various substances in a more intuitive manner. For example, methamphetamine questions in the NSDUH interview are currently grouped in the same module with prescription stimulants. Because most methamphetamine that is currently used in the United States is produced illegally, methamphetamine questions that were previously scattered throughout a number of modules will be housed in a new Methamphetamine module that is separate from the module about nonmedical use of prescription stimulants. In addition to updates for prescription pain relievers and stimulants, prescription drug modules for tranquilizers and sedatives will be updated in the manner described previously. The new definition of nonmedical use of prescription drugs also will undergo further testing for all four prescription drug modules (i.e., pain relievers, tranquilizers, stimulants, and sedatives). Thus, the structure of the prescription drug modules will change to improve measurement of nonmedical use of prescription drugs.

Many of the questions in the back end demographics module will now be self administered. A new module will introduce proxy respondents to the CAI instrument so they can answer questions. Special attention will be paid to the process of transitioning to a proxy respondent, who will answer questions about respondent and household income and health insurance using ACASI.

Finally, a modified question about landline telephones and a new question about cell phones in the home will be tested.

In addition to changes in demographics and the prescription drug modules, electronic pill cards and electronic reference date calendars will be included in the questionnaire to aid respondent recall.

The redesigned NSDUH instrument and methods need to be tested in time for them to be fielded in the 2015 survey. In addition, the Center for Behavioral Health Statistics and Quality (CBHSQ) plans to conduct a field test of the redesigned questionnaire in September through November 2012. Therefore, all modules will be tested through cognitive interviewing and need to be finalized in time to request OMB approval for the September 2012 field test.

Cognitive interviews will be conducted with 40 participants across two rounds of interviews (20 in Round 1 and 20 in Round 2). Qualitative interview data from these participants will be analyzed to evaluate how well potential NSDUH respondents understand the concepts and language of the questions, whether they find them difficult or sensitive to answer, and whether they are able to provide accurate reports of their use of substances and other health issues.

## **2. Use of Information Technology**

Data for these cognitive interviews will be collected in a face-to-face interview setting. Information will be collected electronically via a computer-assisted personal interview (CAPI) on a laptop computer. Audio computer-assisted self-interviewing (ACASI) will not be available in the first round. In Round 2, the questions will be administered using audio computer-assisted self-interviewing (ACASI) for the majority of the interview, using CAPI for the remainder. With participants' permission, the sessions will be audio recorded so the interviewer can reference the recordings when refining his/her notes. The sessions will involve showing participants questions on demographic characteristics, substance use, and other health issues. The interview will focus on questions related to the revised demographic, drug, and proxy modules. For CAPI administration, participants will be asked to read and answer these questions aloud and discuss them with the interviewer. The process for ACASI administration will be similar, except that participants will listen to an audio recording of the questions.

## **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 questionnaire. To date, no duplication of effort has been identified.

#### **4. Consequences if Information Collected Less Frequently**

A dress rehearsal to test this instrument in the field will begin in September, 2013. In order to meet this deadline, reporting of the results from this Phase of cognitive interviewing will need to take place in March, 2012. This project will not be repeated.

#### **5. Consultation Outside the Agency**

CBHSQ has consulted with other experts within SAMHSA, including staff from the Center for Substance Abuse Treatment (CSAT), who helped compile a list of 51 State agency contact persons for additional consultation. These 51 agency representatives became the target sample for the NSDUH State Data Users Survey (OMB No.: 0930-0290). The survey asked about how the states use the data and what additional topics or changes would make the data more useful. We have also requested similar information and guidance from other data users in academia as well as other federal agencies, such as NCHS. Several new questions being tested for the NSDUH are based on questions from the National Survey on Family Growth and the National Health Interview Survey.

There are no unresolved issues resulting from these consultations.

#### **6. Payment to Respondents**

Adult participants will be given \$40 in the form of a Visa gift card for a 90-minute session, and adolescent participants will be given a \$30 gift card. This amount will be sufficient to compensate for the participants' time and any travel expenses incurred (Willis, 2005). Following OMB's direction from the previous Prescription Drug Cognitive interviews (OMB No. 0930-0290), adolescents will receive a lower incentive compared to adults. This decision was made in an effort to avoid introducing an incentive amount that was high enough to coerce adolescents into participating without carefully considering the risk of the research. Given the relationship of the schedule for cognitive interviewing to the schedule for field testing September through November 2013 and the plans for fielding the revised NSDUH instrument by January 2015, significant delays in recruiting participants with a lower incentive amount could adversely affect the timely implementation of these future activities.

The incentive for the interview is mentioned in the following materials: Recruitment Flyers [Attachment A], Recruitment Screening Scripts [Attachment B], Parental Permission 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 cognitive interviews for the NSDUH Questionnaire 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 C], and the participant informed consent forms [Attachment D] 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 (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.

All internal communication regarding a participant will include only 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). Both the electronic files and hardcopies containing identifying information will be destroyed within 4 weeks after CBHSQ approves the final report.

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, we will collect the age, phone number, city of residence, any significant physical limitations that would preclude participation, participation in other research studies, and the prescription drug use of adults 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. During the cognitive interviews, we will collect the age and gender of all participants but only to inform the CAI program which questions to display and to tailor

wording. No links to individuals will be preserved in the cognitive interview report.

## **8. Questions of a Sensitive Nature**

Many of the questions to be tested concern topics that are likely to be of a sensitive nature, including nonmedical use of prescription pain relievers, stimulants, tranquilizers and sedatives in the past 30 days and past 12 months, alcohol use by persons under the age of 21, tobacco use by persons under the age of 18, and use of illegal drugs by participants of all ages. Other health questions ask about topics that are likely to be considered sensitive by participants of all ages (e.g., pregnancy, STDs, HIV/AIDS). Consequently, some of these questions could be distressing for some respondents.

Measures will be taken to reduce risks to the respondents. For respondents interviewed on-site at treatment facilities, arrangements will be made with the programs to have a counselor on call at the facility during the times when interviews will be conducted, in case any treatment clients participating in the study become upset by the interview questions and want to speak with a counselor. For respondents being interviewed at RTI facilities who become upset with the questions and would like to speak with someone, referral options include their health care provider (if applicable) and also the Lifeline Network (1-800-273-TALK [8255]). Respondents recruited from outside of substance abuse treatment who request information on substance abuse treatment options can call the Substance Abuse and Mental Health Service Administration's (SAMHSA's) 24-hour toll-free Treatment Referral Helpline (1-800-662-HELP).

In addition, all participants regardless of age will be reminded periodically not to report anything that could identify another person. At the conclusion of the tutorial prior to the main interview (page 16 Attachment E), the interviewer also will give examples of ways that a participant may talk about another person and examples of ways not to talk about someone. As a further protection, the interviewer will interrupt participants who appear to be ready to report something identifying about themselves or someone else in responding to a question or probe.

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 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**

Forty participants will be interviewed in this study. It is expected that approximately 50 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 5 minutes per participant. It is estimated that the average amount of time required to conduct each cognitive interview will be approximately 90 minutes.

Both the recruitment and cognitive interviewing phases for both rounds of interviews for this study will span approximately 3.5 months over the months of November 2011 through early February 2012.

The respondent burden for this study is shown in Table 1 below. The hourly wage of \$14.71 was calculated based on weighted data from the 2009 NSDUH respondents' personal annual income.

**Table 1. Estimated Burden for Cognitive Interviews for Questionnaire Redesign**

<b>Activity</b>	<b>Number of Respondents</b>	<b>Responses per Respondent</b>	<b>Average Burden per Response (Hours)</b>	<b>Total Burden (Hours)</b>	<b>Hourly Wage Rate</b>	<b>Total Hour Cost</b>
Screening	50	1	0.083	4.15	\$14.71	\$61.05
Full Cognitive Interviews	40	1	1.500	60.00	\$14.71	\$882.60
Proxy Only Interviews	10	1	.25	2.5	\$14.71	36.78
<b>TOTAL</b>	<b>50</b>	<b>-</b>	<b>-</b>	<b>66.65</b>	<b>-</b>	<b>\$980.43</b>

**10. Estimates of Annualized Cost to the Government**

Total costs associated with the cognitive interviews for the NSDUH Prescription Drug Redesign are estimated to be \$144,853 over a 12-month performance period. Of the total costs, \$121,075 is for study design, preparation of materials for testing, recruiting, conducting the cognitive interviews, analysis and report/publication writing, and approximately \$23,778 represents SAMHSA costs to manage/administrate the survey.

## 11. Time Schedule, Publication and Analysis Plans

The results of the cognitive interviews for the NSDUH Questionnaire Redesign will be used to gauge the impact of wording changes and question additions and deletions that are being considered for the redesigned NSDUH questionnaire. 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 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 the 2012 field test.

The time schedule for the cognitive interviews for the NSDUH Questionnaire Redesign is included in Table 2 below.

**Table 2. Schedule for Cognitive Interviews for Questionnaire Redesign**

<b>Subtask</b>	<b>Due Date</b>
Recruiting for cognitive interviews begins	November 1, 2011
Round 1 cognitive interviews begin	November 1, 2011
Round 2 cognitive interviews begin	January 16, 2012
All cognitive interviews completed	February 3, 2012
Final cognitive interview report completed	April 10, 2012

## 12. Respondent Universe and Sampling Methods

The sample of 40 participants to be recruited is non-probability based. It will consist of volunteers who are screened and determined to meet recruitment criteria. Table 3 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. Individuals from treatment programs who respond to the recruitment in Round 1, but were not interviewed, could be placed on a waiting list and may still be eligible to be interviewed in Round 2.

**Table 3. Targeted Sample Sizes per Cognitive Interview Round, by Location, Age Group, and Recruitment Source**

<b>Group/Recruitment Source</b>	<b>Cognitive Interview Round</b>		<b>Total</b>
	<b>Round 1</b>	<b>Round 2</b>	

<b>Location</b>	20	20	40
Research Triangle Park, NC	8	8	16
Washington, DC	5	5	10
Chicago, IL	7	7	14
<b>Adults Aged 18 or Older</b>	10	10	20
General Population	7	7	14
Substance Abuse Treatment	3	3	6
<b>Youths Aged 12 to 17</b>	10	10	20
General Population	10	10	20
Substance Abuse Treatment	0	0	0
<b>Total</b>	20	20	40
General Population	17	17	34
Substance Abuse Treatment	3	3	6

A total of 40 interviews across both 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 on-site at their program or at a local RTI office.

The objectives mentioned previously for the cognitive interviewing require the study to include people who match selected characteristics of the target population the NSDUH is trying to reach. Education level and veteran status (for adults) also are important for testing participant understanding and interpretations of the questions.

**Table 4. Sample Targets for Selected Characteristics, by Cognitive Interview Round**

<b>Group</b>	<b>Cognitive Interview Round</b>	
	<b>Round 1</b>	<b>Round 2</b>
<b>Adults Aged 18 or Older</b>	10	10
<b>Prescription Drug Use, Past 12 Months<sup>1</sup></b>		
Any pain reliever	At least 1	--
Any stimulant	At least 1	--
Any sedatives	At least 1	--
Any tranquilizers	At least 1	--
<b>Education</b>		
High school diploma, GED, or lower	At least 1	At least 1
<b>Gender</b>		
Male	At least 2	At least 2
Female	At least 2	At least 2
<b>Military Status</b>		
Military Veteran	At least 2	At least 3
<b>Youths Aged 12 to 17</b>	10	10
<b>Gender</b>		
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, a military veteran who had a high school diploma, GED, or lower would contribute toward satisfying the targets for both military status and education.

<sup>1</sup> 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.

Targets for characteristics closer to the top of the list of the recruitment screener [Attachment B] 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 re-contacted to fill the vacant interview slots to maximize the attempt to obtain the targeted number of participants in a given round.

To aid in the efficient collection of information on the new proxy transition being tested for NSDUH, adolescent and parent pairs will be recruited. During all adolescent interviews, the parent or guardian will complete an ACASI tutorial, income and health insurance questions. Ideally, that parent or guardian will then complete a full interview with the interviewer. However, recruitment of parents from treatment centers or parents who are veterans and also have adolescent children willing to participate may become difficult. In the event that we complete interviews with adults who are not paired with their children, we will need to complete interviews with children whose parents will not be given a full interview. In this case, the parent will answer only the proxy questions for health insurance and income and will not participate in a full interview. This parent will not receive an incentive, but will be read a short consent form to each of these parents prior to completion of the proxy questions.

Because persons who have had considerable prior experience with survey research may bias the data and conclusions, persons will be ineligible if they have participated in more than one prior research study in the past 12 months.

Because the cognitive interview procedure will require participants to see the questions on the laptop computer screen (or listen to them in Round 2), 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 2010, for example, more than 66,000 of the final completed interviews (96.6 percent) were conducted in English, and about 2,300 (3.4 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 20 adult participants and up to 20 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, military status, participation in prior research studies, the presence of any physical limitations that would preclude their effective participation, and use of prescription pain relievers, stimulants, sedatives, or tranquilizers in the 12 months prior to the screening interview. When the recruiter determines that a caller in Round 1 or 2 is an adolescent, the recruiter will obtain permission over the telephone from their parent or legal guardian. [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. Eligible adult or adolescent respondents will be scheduled for a 90-minute 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 the interviewing phase, individuals on the “will call” list may be called to ask if they are available, such as 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 their interview, he or she will be greeted and asked to listen to instructions and informed consent/assent information from the interviewer, and parental permission when applicable [Attachments C and D]. All cognitive interviews will be audio recorded upon consent of each participant and a subset may be observed by a staff member, again upon consent of each participant. Participants will have the right to decline to be audio recorded and/or observed without being excluded from participation.

Before the interview begins, the participant will be read the Participant Informed Consent [see Attachment E]. The interview will commence after the participant has given his or her consent. The interviewer will begin by asking the participant for demographic information (to determine how the CAI program should route the participant through 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 an abbreviated version of the NSDUH core drug questions. These include questions about the use of tobacco products, alcohol, marijuana, cocaine, heroin, methamphetamines, hallucinogens and inhalants as well as nonmedical use of prescription drugs. Some of these questions have been reworded and are being presented in a new format for these interviews. However, the substantive measures from the NSDUH core drug questions have not changed.

Answers that participants give to questions about use of substances will determine whether they are asked more detailed questions for these substances [see Attachment E]. In all rounds of cognitive interviewing, participants will receive questions about health service utilization, health conditions, education, and employment following any questions they receive about substances.

All participants will be asked questions about health insurance and income. However, for adolescent respondents, an adult proxy will complete this section and the interviewer will have the proxy complete a brief ACASI tutorial before answering these questions. This new proxy transition is also one of the items being evaluated in these interviews.

After these modules, the interviewer will ask some additional demographic questions before completing the interview.

For each set of questions, participants who are administered the questions in CAPI will be instructed to read the questions aloud and discuss them with the interviewer; participants will listen to the voice recording of the ACASI questions and then answer. 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 and Lessler 1991). Interviewers will be provided with a series of probes and questions that will further explore the quality of 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 in Attachment E. However, the interviewer requires the latitude to deviate from 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, given a \$40 or \$30 Visa gift card as appropriate for their time, and will be given a participation receipt form [Attachment F].

**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 interview location and an opportunity to ask any questions about the purpose or logistics of the study. The \$40 adult or \$30 adolescent incentive will also help ensure participation. As an additional procedure to maximize the response rates, prospective participants who were placed on a “will call” list at the end of Round 1 of the cognitive interviewing may be eligible to be recontacted for enrollment in the next round of interviews.

**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 - Cognitive Interview Recruitment Flyers

Attachment B - Cognitive Interview Recruitment Screening Scripts

- Attachment C - Cognitive Interview Participant Informed Consent/Assent Forms
- Attachment D - Cognitive Interview Parental Permission and Informed Consent Form
- Attachment E - Protocol for Cognitive Interviews
- Attachment F - Cognitive Interview Receipt for Participation

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