



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: **Resubmission of Health Information National Trends Survey 4 (HINTS 4)
Cognitive Testing of HINTS-FDA Instrument**
Generic Sub-study under “**Questionnaire Cognitive Interviewing and
Pretesting,**” (OMB No. 0925-0589; Expiration Date: 4/30/2014)

The National Cancer Institute’s (NCI) Division of Cancer Control and Population Sciences (DCCPS), Behavioral Research Program (BRP) proposes conducting cognitive testing of a HINTS-related data collection instrument developed in conjunction with the FDA. In response to the June 6, 2013 meeting with OMB staff, the HINTS team coordinated efforts with other Federal partners to inform the development of the instrument to be tested and has explored CDC’s Q-Bank database of cognitive testing reports (<http://wwwn.cdc.gov/qbank/home.aspx>) to identify tobacco and health communication items that previously have been cognitively tested for other national surveys. The proposed cognitive testing plan has been adjusted so that:

- Of the total number of items on the proposed instrument, only 39% are going to be tested during this round of cognitive testing. The other 61% of questions are included to provide the respondent with a context for their response and will not be probed at all.
- Of the 63 items to be tested, 63% (40 items) are on the topic of tobacco. The other 37% of the questions to be tested are related to other FDA concerns such as dietary supplements and medical products.
- Of the 40 tobacco-related items to be tested, **90% of the items are new and have never been included on any other Federal survey.** The other 10% (n=4) are modified versions from other surveys and have not been tested or fielded in the proposed form.

The tobacco items to be tested under this generic clearance request have never been used or tested in this form and would need to be tested prior to administration in any Federal study. Specifics about the testing plan and instruments are detailed below.

Background, Need and Use of Information. All HINTS-related materials undergo testing prior to administration. The previous pretesting conducted under HINTS and OMB clearance numbers are outlined in Table 1 below.

Table 1: Pretesting Already Conducted for HINTS 4

Focus Groups for the development of cover letters	OMB No. 0925-0589-06, exp. 5/31/11
Cognitive testing of Cycle 1 instrument	OMB No. 0925-0589-09, exp. 5/31/11
Pilot Test	OMB No. 0925-0589-10, exp. 5/31/11
Cognitive testing of Cycle 2 instrument	OMB No. 0925-0589-03, exp. 4/30/14
Cognitive testing of Cycle 3 instrument	OMB No. 0925-0589, exp. 4/30/14

The HINTS data collection program addresses many critical health research and programmatic needs related to health communication. There is an ongoing effort to include input from subject matter experts in the broader HINTS research and data user community, including partners from other Federal agencies such as the FDA. The core of HINTS is the health communication construct, which is unique to the HINTS program and allows investigators to assess how public information exposure and information seeking influence health knowledge, attitudes, and behavior at the population level.

As noted in earlier sub-study submissions, cognitive testing of the planned HINTS-FDA questionnaire is essential to identify problems in question wording, context or order effects, as well as response difficulties resulting from the design and layout of the mail form. Although NCI is working towards having a full HINTS-FDA data collection effort (with OMB approval), the results of the proposed cognitive testing will facilitate improvements to both the questions and the design of the questionnaire for use by any Federal agency.

Commitment to Sharing Study Results with Federal Partners. In the spirit of collaboration and coordination, we are in the process of adding all of the HINTS 4 cognitive testing reports to Q-Bank so that others may benefit from what we’ve learned from testing a range of health communication- and tobacco-related items, as well as items related to other HINTS constructs such as cancer screening, genetic testing, and preventive health behaviors, among others. We plan to continue such efforts toward coordination by submitting the HINTS-FDA cognitive testing reports to Q-Bank when they are completed, and by sharing the results of our testing and resultant item construction decisions with other Federal partners who are planning tobacco-related data collections.

Participants. Recruitment for the proposed testing will take place in the same way as was conducted for Cycle 1 (OMB No. 0925-0589, approved February 2011), Cycle 2 (OMB No. 0952-0589, approved July 2012), and Cycle 3 (OMB No. 0925-0589, approved December 2012). Participants for the proposed cognitive interviews will be recruited from the non-institutionalized adult household population. Ten of the 35 cognitive interviews will be conducted with adults who speak primarily Spanish at home.

Data Collection Methods. The methods for the proposed testing will follow the same pattern that was used for the other HINTS cycles. All cognitive interviews will be done in person and each will take 90 minutes. The English language interviews will be conducted at Westat and Spanish language interviews will be conducted at Eureka Facts, both located in Rockville, MD. Interviews will be audio recorded with the respondent's consent and participants will receive \$50 for their participation. This amount has been successfully used to recruit respondents for previous HINTS cognitive interviews and we anticipate that a reduced amount would otherwise increase recruitment costs.

Cognitive Interview Materials. Westat will use a semi-structured protocol for conducting the cognitive interviews, focusing primarily on comprehension issues with those questions new to the HINTS-FDA. See **Attachment A-1** for the proposed questionnaire content for testing in English and **Attachment A-2** for the proposed questionnaire content in Spanish (preliminary translation). These attachments reflect a coordinated effort in which proposed items were compared to other national surveys in order to enhance harmonization and reduce duplication with other tobacco-related data collection efforts across the Federal government. **Attachment A-3** provides a spreadsheet that compares tobacco-related constructs and items planned for HINTS-FDA to other Federal surveys.

Attachment B-1 contains for the proposed interview protocol in English and **Attachment B-2** contains the proposed interview protocol in Spanish. **Attachment C-1** shows the consent form planned for use with the cognitive interviews in English and **Attachment C-2** shows the consent form in Spanish.

Participant Recruitment. Recruitment techniques will be the same as were used for Cycles 1, 2 and 3, although it is anticipated that more focus will be placed on recruiting current smokers. Westat and Eureka Facts will recruit participants for the cognitive interviews using sources such as CraigsList and print advertisements in local community papers (**see Attachment D**). When interested individuals call the toll-free number, recruitment staff will explain the purpose of the project, eligibility criteria, and what is involved in participating. Recruitment staff will screen individuals for participation (**see Attachments E-1 and E-2**). One week before the interview, recruitment staff will send individuals who have agreed to participate in the English interviews a reminder letter (**see Attachment F**) and directions to the Westat facility. We have found it unnecessary to send reminders to the Spanish participants.

Data Analysis. Westat will analyze the data using qualitative analysis methods. Cognitive interview summaries will be analyzed to identify issues common across respondents or supported by theory to guide the final question wording and form design construction.

IRB Review. The cognitive testing activities and materials outlined in this memo were approved by Westat's IRB (**see Attachment G**).

Privacy Considerations. As necessary for recruitment, we will collect personally identifying information (PII). The completed recruitment questionnaires will be stored in a locked cabinet/drawer. The keyed data from the questionnaires will replace individuals' names with unique ID numbers for electronic storage. The mapping between the person's name and the associated ID number will be stored in a separate file. Both the mapping and the electronic version of the recruitment responses will be stored on a restricted-access drive within the Westat

firewall. Both the paper and electronic versions of the recruitment information will be destroyed within two weeks of the completion of the final report covering the cognitive testing research.

Respondent Burden and Costs. The table below displays the burden estimate for this data collection effort. We expect to include up to 35 participants across the English- and Spanish-language cognitive interviews. Those interviews will last up to 90 minutes each. The total respondent burden for this effort is estimated to be 58 hours. There have been 305 hours of burden used to date, out of a total of 6,000 hours approved for Generic clearance 0925-0589.

Table 3: Estimates of Hour Burden

Type of Respondents	Form	Number of Respondents	Number of Responses Per Respondent	Average Time (in hours)	Total Burden Hours
General public	Screening Questionnaire (Attachments E-1/2)	60	1	5/60	5
	Questionnaire Content and Interview Protocol (Attachments A-1/2 and B-1/2)	35	1	1.5	53
Total					58

Thank you for your consideration of this proposed sub-study.

Attachments (attached in a separate file)

- A-1: HINTS 4 Questionnaire Content (HINTS-FDA) – English
- A-2: HINTS 4 Questionnaire Content (HINTS-FDA) – Spanish
- A-3: Spreadsheet Comparing HINTS-FDA constructs and items to other Federal surveys
- B-1: Interview Protocol – English
- B-2: Interview Protocol – Spanish
- C-1: Consent Form – English
- C-2: Consent Form – Spanish
- D: Recruitment Advertisements
- E-1: Screening Questionnaire – English
- E-2: Screening Questionnaire – Spanish
- F: Reminder letter to Cognitive Interview Participants
- G: Westat IRB Approval