



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: February 11, 2014 (originally submitted December 4, 2013)

To: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
Susan Queen, ASPE, HHS
Seleda Perryman, Report Clearance Officer, NIH
Vivian Horovitch-Kelley, PRA OMB Clearance Liaison, NCI

From: Bradford Hesse, Project Officer,
Health Information National Trends Survey (HINTS),
Division of Cancer Control and Population Sciences,
National Cancer Institute/NIH

Subject: Health Information National Trends Survey 4 (HINTS 4) Cognitive Testing of Cycle 4 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 formative research for the fourth iteration of the Health Information National Trends Survey (HINTS 4). Clearances granted for HINTS 4 data collection are outlined in Table 1 below.

Table 1: Data Collection Already Conducted for HINTS 4

Cycle 1 data collection	Clearance granted 10/17/11 for Cycle 1. At the same time, clearance granted for Cycles 2, 3, and 4 based on the agreement that HINTS staff would contact OMB to determine whether a change request or a revision should be submitted. Cycle 3 Clearance granted 8/14/2013 as a Change request.	OMB No. 0925-0538, exp. 10/31/14
Cycle 2 data collection		
Cycle 3 data collection		
Cycle 4 data collection		

NCI proposes conducting cognitive testing of the Cycle 4 data collection instrument. Because the Cycle 4 instrument includes some questions from Cycles 1, 2 and 3 instruments that have already been tested, the testing proposed in this memo will focus on items developed specifically for Cycle 4. The previous pretesting conducted under HINTS and OMB clearance numbers are outlined in Table 2 below.

Table 2: 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. 0925-0589-05, exp. 4/30/14
Cognitive testing of FDA cycle instrument	OMB No. 0925-0589-06, exp. 4/30/14

Background, Need and Use of Information. As noted in earlier sub-study submissions, 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. Thus, cognitive testing of the survey 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. The results of the cognitive testing will facilitate improvements to both the questions and the design of the questionnaire for use in Cycle 4 of HINTS.

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 31, 2012). Participants for the proposed cognitive interviews will be recruited from the non-institutionalized adult household population. Eleven of the 33 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 Cycles 1, 2 and 3. All cognitive interviews will be done in person. 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 be given \$50 as a thank you for their participation. This thank you amount is the same as has been used for conducting previous cognitive testing for HINTS over the past several years and it has been successful in retaining respondents throughout the testing time frame.

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 Cycle 4 data collection in HINTS 4. 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). **Attachment B-1** contains for the proposed interview protocol in English and **Attachment B-2** has 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.

Tobacco Items. Like all HINTS instruments, the HINTS Cycle 4 instrument is primarily about health information seeking behaviors and beliefs about cancer. The Cycle 4 instrument also focuses on the use of electronic medical records, respondent experience with the medical

establishment, and knowledge of clinical trials and genetic testing. As demonstrated in the below table, the Cycle 4 instrument has a very limited number of tobacco-related items.

Number of tobacco questions included in HINTS

Year of Administration	Total number of items	Number of tobacco items	Percent of items about tobacco
HINTS 1: 2003	223	16	7.2%
HINTS 2: 2005	195	28	14.4%
HINTS 3: 2007	185	19	10.3%
HINTS 4, Cycle 1: 2011	205	2	1.0%
HINTS 4, Cycle 2: 2012	196	11	5.6%
HINTS 4, Cycle 3: 2013	210	15	7.1%
HINTS 4, Cycle 4: 2014 (proposed)	289	18	6.2%

Participant Recruitment. Recruitment techniques will be the same as were used for Cycles 1-3. Contractors will recruit participants for the cognitive interviews using sources such as Craig’s List 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 for use in the fourth cycle of data collection of HINTS 4.

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

Privacy Considerations. As a necessity 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 have up to 33 people participate 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 68 hours. There have been 388 hours approved to date, out of a total of 6,000 hours requested.

Table 3: Estimates of Hour Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Burden Hours
General Public	Screening Questionnaire (Attachments E-1/2)	60	1	15/60	15
	Consent Form (Attachments C-1/2)	33	1	5/60	3
	Questionnaire Content and Interview Protocol (Attachments A-1/2 and B-1/2)	33	1	1.5	50
Total					68

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

Attachments (attached in a separate file)

- A-1: Instrument to be Tested - HINTS 4 Questionnaire (Cycle 4) – English
- A-2: Instrument to be Tested - HINTS 4 Questionnaire (Cycle 4) – Spanish
- 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