



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: January 12, 2012

To: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, DHHS
Seleda Perryman, Report Clearance Officer, NIH
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMA

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 2 Instrument** (Generic Sub-study under “Questionnaire Cognitive Interviewing and Pretesting,” (OMB No. 0925-0589-03; 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)¹. NCI proposes conducting cognitive testing of the Cycle 2 data collection instrument. Because the Cycle 2 instrument includes some questions from the Cycle 1 instrument that have already been tested (OMB No. 0952-0589-10, exp 5/31/11), the testing proposed in this memo will focus on items developed specifically for Cycle 2.

Background, Need and Use of Information. As noted in earlier sub-study submissions², 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 new 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 2 of HINTS³.

¹ HINTS 4 (OMB No. 0925-0538, exp. Oct 31, 2014).

² OMB Nos. 0925-0589-06, -09 and -10, exp. 5/31/11.

³ Separate OMB generic sub-study clearance packages will be submitted for testing the mail questionnaires associated with cycles 3 and 4 data collections.

Participants. Recruitment for the proposed testing will take place in the same way as was conducted for Cycle 1 (OMB No. 0925-0589-09). 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 Cycle 1. 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 receive \$50 as a thank you for their participation.

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 2 data collection in HINTS 4. Some new questions have two proposed alternatives for cognitive testing. We will create two different forms, with one version of each question in a form. Respondents will be shown the alternative version to that included on their questionnaire as part of a follow-up probe. See **Attachment A** for the proposed questionnaire content for testing (showing both versions of each question with two versions included in testing) and **Attachment B** for the proposed interview protocol. **Attachment C** shows the consent form planned for use with the cognitive interviews. The Spanish-language materials will reflect the same content as the English language materials.

Participant Recruitment. Recruitment techniques will be the same as were used for Cycle 1. Westat and Eureka Facts 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 Attachment E**). One week before the interview, recruitment staff will send individuals who have agreed to participate a reminder letter (**see Attachment F**) and directions to the Westat facility.

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 second cycle of data collection of HINTS 4.

IRB Review. Approval or exemption from both Westat and NCI IRBs is obtained prior to the initiation of any testing. 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) in the form of name, mailing address, and phone number in order to allow researchers to send confirmation letters to respondents and to contact them prior to the interview if necessary. 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 65 hours. To date, a total of 107 burden hours have been used of the 3600 hours (less than 3%) that were granted in April, 2011 for OMB No. 0925-0589.

Estimates of Hour Burden

Type of Respondents	Instrument	Maximum Number of Respondents	Frequency of Response	Estimated Burden (minutes/hour)	Total Burden Hours
General public	Screening Questionnaire (Attachment E)	60	1	15/60 (0.25)	15
	Questionnaire Content and Interview Protocol (Attachments A and B)	33	1	90/60 (1.5)	50
Total		93			65

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

Attachments (attached in a separate file)

- A: HINTS 4 Questionnaire Content (Cycle 2)
- B: Interview Protocol
- E: Screening Questionnaire

Attachments (attached below)

- C: Consent Form
- D: Recruitment Advertisement
- F: Reminder letter to Cognitive Interview Participants
- G: Westat IRB Approval Letter

Attachment C: COGNITIVE TESTING CONSENT FORM (English)

We would like to talk with you about a questionnaire Westat is developing as part of the Health Information National Trends Survey (HINTS). Westat is conducting this research for the U.S. Dept. of Health and Human Services (DHHS). The questionnaire asks about health-related topics. By taking part in this interview, you are helping us evaluate how easy or difficult the questions are to understand and answer. Your opinions will help us improve the questionnaire.

- Your participation is completely voluntary. You may stop at any time, and you can skip any questions you do not wish to answer.
- All information obtained during this study will be treated as private under the Privacy Act and will only be used to develop and improve the questionnaire. We will not share your answers with anyone outside of the HINTS project research team.
- The interviewer will audio record the discussion and take notes. In addition, project researchers may observe the interview. The researchers will destroy the audio recording as soon as they complete the questionnaire development process.
- The interview should take about an hour and a half.
- The report summarizing the findings will not contain any names or identifying information.
- You will receive \$50 cash as a token of our appreciation for completing the session.
- If you have questions about this research, please contact Brad Hesse, the Principal Investigator at (301-594-9904; hesseb@mail.nih.gov). If you have questions about your role as a research participant, please contact Sharon Zack, the Westat Institutional Review Board Administrator (301-251-1500; sharonzack@westat.com).
- A copy of this consent form has been provided for your records.

If you agree to participate in this interview, please sign the following statement.

I have read this consent form and understand the proposed project. I consent to participate in this study and to have the interview audio taped.

Participant's Signature

Researcher's Signature

Printed Name

Printed Name

Date

Attachment C: COGNITIVE TESTING CONSENT FORM (Spanish)

Nos gustaría hablarle acerca de un cuestionario que Westat está desarrollando como parte de la Inspección de Información de Encuestas de Salud Nacional (HINTS por sus siglas en inglés). Westat está conduciendo este estudio para el Departamento de Salud y Servicios Humanos (DHHS por sus siglas en inglés). El cuestionario hace preguntas acerca de temas relacionados con la salud. Al tomar parte de esta entrevista, nos ayudará a evaluar que tan fácil ó difícil de entender y responder son las preguntas. Sus opiniones nos ayudarán a mejorar el cuestionario.

- Su participación es completamente voluntaria. Usted puede detenerse en cualquier momento, y puede dejar de responder cualquier pregunta(s) que no desee responder.
- Toda la información obtenida durante este estudio se mantendrá privada como lo contempla la Ley de Privacidad y sólo se usará para crear y mejorar el cuestionario. No compartiremos sus preguntas con nadie fuera del equipo de investigación del proyecto HINTS.
- El entrevistador grabará la discusión vía audio y tomará notas. Además, investigadores del proyecto podrán observar la entrevista. Los investigadores destruirán la grabación de audio tan pronto completen el proceso de desarrollo del cuestionario.
- La entrevista toma cerca de una hora y media.
- El reporte que resume la el estudio no contendrá ningún nombre ó información de identificación.
- Usted recibirá \$50.00 en efectivo como muestra de agradecimiento por completar la sesión.
- Si tiene preguntas acerca de éste estudio, por favor contacte a Brad Hesse, el Investigador Principal al (301-594-9904; hesseb@mail.nih.gov). Si tiene preguntas sobre su papel como un participante en el estudio, por favor contacte a Sharon Zack, la administradora del comité de revisión del Instituto Westat (301)-251-1500; sharonzack@westat.com).
- Una copia de este formulario de consentimiento has sido provisto para sus registros.
Si usted está de acuerdo en participar en esta entrevista, por favor firme la siguiente declaración.

He leído este formulario de consentimiento y entiendo el proyecto propuesto. Doy mi consentimiento a participar en este estudio y a que la entrevista sea grabada vía audio.

Firma del Participante

Firma del Investigador

Nombre en letra de molde

Nombre en letra de

Fecha

Attachment D: **SAMPLE RECRUITMENT ADVERTISEMENT**

Health Information Study
Receive \$50

Westat is looking for study participants to review survey questions about how people find information about health topics as well as questions about health in general. Interviews will be conducted at Westat's Rockville office and will last approximately 90 minutes.

We are interested in adults at least 18 years of age or older. All participants receive \$50 dollars for their time. Call 800-1-888-XXX-XXXX and say you are calling about the Health Information Study. Please leave a name, telephone number and a good time to reach you.

SE NECESITAN PARTICIPANTES PARA ESTUDIO

EurekaFacts, una compañía de estudios en Rockville, MD, está buscando personas mayores de 18 años para dar su opinión acerca de un estudio sobre salud. La duración de la sesión: Aproximadamente 90 minutos y se llevará a cabo en nuestra oficina en Rockville.

Personas elegidas para participar en el grupo de discusión recibirán \$50 en efectivo

Para más información sobre el estudio llame (240) 403-4800, ext. 210.

Llame hoy

(240) 403-4800, ext 210

O Escribanos a

wurzela@EurekaFacts.com

ATTACHMENT F: REMINDER LETTER



An Employee-Owned
Research Corporation

1600 Research Boulevard
Rockville, MD 20850-3129
tel: 301-251-1500
fax: 301-294-2040
www.westat.com

[Date]

Dear [name],

Thank you for agreeing to participate in our study on health-related topics. Here are details to remind you where and when to appear for the interview session. The session will take about an hour and a half. You will receive \$50 as a token of gratitude for your participation in the study.

DATE: XX/XX/XXXX

TIME: XXpm

LOCATION: Westat
Conference Center
1600 Research Boulevard
Rockville, MD 20820

Directions and a map are enclosed.

Kindly allow enough time for travel so that we may begin on time. There will be designated parking spaces marked "(Study)" in the Conference Center Parking lot. Someone will meet you in the lobby of the 1600 building.

If you need further information, please call me at the office (301) XXX-XXXX.

We look forward to seeing you and thank you in advance for your assistance.

Sincerely,
[Westat staff]

APPENDIX G: Westat IRB Approval Letter



Westat

An Employee-Owned
Research Corporation

Memo

Date: January 10, 2012
To: Terisa Davis, Project Director
From: Kerry Levin, Chair, Westat IRB
Subject: Amendment Approval of HINTS 4, Project 8861.01.04
FWA 5551

Kerry Levin

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **HINTS 4, Project 8861.01.04**. The Westat IRB reviews all studies involving research on human subjects. This study received initial approval on November 11, 2010.

This request was to approve a new instrument and protocol. This round of testing will be held with 33 respondents: 22 in English and 11 in Spanish.

IRB regulations permit expedited review of minor changes to previously approved activities [45 CFR pt. 46.110 (b)]. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- If you received a conditional approval, project activities (e.g., recruiting, enrolling) may not begin until your responses have been received by the IRB and final approval is granted.
- You are required to submit this study for a continuing review on or before November 11, 2012.
- In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Nancy Weinfield