



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: November 29, 2010

To: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
Marilyn Tuttleman, NIH Project Clearance Officer, OPERA
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMAA

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) Advance Materials Focus Groups
Generic Sub-Study under “Questionnaire Cognitive Interviewing and Pretesting,” OMB No. 0925-0589-06, Expiration Date: 5/31/2011

The National Cancer Institute’s (NCI) Division of Cancer Control and Population Sciences (DCCPS), Behavior Research Program (BRP) proposes conducting formative research prior to the fourth iteration of the Health Information National Trends Survey (HINTS 4) (OMB No. 0925-0538). Specifically, NCI proposes conducting focus group research for the purpose of obtaining feedback on alternative message content included in the survey mailing materials. Conducting this research is critical to successful recruitment efforts and to gaining the cooperation of thousands of household respondents for HINTS 4. Results will be used to inform the development of the content for the following correspondence with sampled households: the advance letter, the cover letters sent along with the HINTS 4 questionnaires, the reminder postcard sent to households who do not initially respond to the survey request, and the Questions and Answers (Q&A) document included with the questionnaire mailing packages.

Background, Need and Use of Information. The HINTS data collection program addresses many critical health research and programmatic needs. The HINTS program monitors changes in the rapidly evolving field of health communication. Survey researchers are using the data to understand how adults 18 years and older use different communication channels, including the Internet, to obtain vital health information for themselves and their loved ones. Program planners are using the data to understand and address barriers to health information usage across populations, and to create more effective communication strategies. Finally, social scientists are using the data to refine their theories of health communication in the information age and to offer new and better recommendations for reducing the burden of cancer throughout the population. HINTS creates and publishes *HINTS Briefs* showcasing results to ensure that findings from HINTS research can be used to develop evidence-based policies, programs, and practices relevant to health communication at the national, state, and local level.

These important scientific and program functions require that the HINTS program engage in efforts to develop and improve data collection protocols that will result in high data quality. Based on experimentally controlled methods research conducted as part of the previous round of HINTS, HINTS 4 will use an entirely mail-based data collection procedure that collects data in 4 cycles with 4 independent samples. Thus, the proposed formative research seeks to identify the most effective messages to use with the HINTS 4 mailing materials to encourage the participation of all sampled households, improving overall response rate and diminishing the chances of systematic nonresponse specific to certain subpopulations.

Participants and Recruitment. Focus group participants will be recruited from the non-institutionalized adult household population. Neither Westat nor NCI employees will be eligible to participate in the focus groups. Two of the four focus groups will be conducted with adults who speak primarily Spanish at home. HINTS 4 will include a Spanish-language questionnaire and supporting materials so evaluative information about the effectiveness and clarity of those materials for the Spanish speaking population is needed. The English-speaking focus groups will recruit a racially diverse population. Both the English- and Spanish-speaking focus groups will recruit participation from adults representing a variety of educational attainment levels.

Westat, along with their subcontractor EurekaFacts, will recruit participants for the focus groups. Recruiters will place advertisements on Internet sources such as Craig's List, and will print advertisements in local community papers around the Washington DC metropolitan area. In addition, local adult education programs will be contacted to seek permission to distribute flyers at one or more classes that cater to populations with less than a college education. All advertisements will include a toll-free phone number for those interested in finding out more about participation.

EurekaFacts will handle recruitment of the Spanish-speaking participants. As a professional focus group and market research firm specializing in Spanish-speaking and other hard-to-reach populations, EurekaFacts will advertise for participants in Spanish-market papers and locations for which they have had prior success in recruiting focus group and one-on-one interview participants. Additionally, EurekaFacts may draw from eligible Spanish-speaking respondents within their established recruitment database, providing individuals have not participated in a similar focus group in the last 12 months. All advertisements will include a toll-free number dedicated to Spanish language calls.

When interested individuals call either 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 in the focus groups (**see Attachment 6A**). One week before the focus group session, recruitment staff will send individuals who have agreed to participate a reminder letter (**see Attachment 6B**), and directions to the Westat facility. Recruitment staff will attempt to contact all participants by phone 1–2 days prior to the focus group to remind them of their appointment.

Data Collection Methods. The focus groups will be conducted in the focus group facilities at Westat in Rockville, MD. All the focus groups will be conducted by professionally trained

moderators. Two of the four total focus groups will be conducted by a bilingual (Spanish/English) moderator and the other two conducted by an English-speaking moderator.

In addition to the moderator, each focus group will include an assistant who will take notes, gather informed consent forms, distribute respondent payments and manage other administrative details. Each focus group will last up-to 90 minutes, and all participants will be asked to arrive a few minutes early to review and sign the consent form. All focus groups will be video and audio recorded with the consent of participants. Focus group moderators will use the session notes and recordings to summarize the sessions. The Spanish speaking moderator will do the initial summary in Spanish, and then translate to English for NCI and other project staff. Participants of the focus groups will receive \$50.00 as a thank you for their participation. The amount of this incentive is slightly higher than average to account for time spent in screening and reviewing the consent form, travel time (the amount of time required by participants for a 1.5 hour focus group is close to 2 hours when travel is counted), and travel expenses (Westat is not located on the Metro) .

Focus Group Moderator Materials. Westat will test the following materials as part of the focus groups (see **Attachment 6C for the full set of materials**):

- two versions of the cover letter mailed with the questionnaire packets, plus the version used in the 2007 HINTS mail sample,
- two versions of a refusal conversion letter mailed to households who don't initially respond
- a set of Frequently Asked Questions, and
- alternative facts that could replace or add to the relevant content of the letters under consideration.

The Spanish-language materials will reflect the same content as the English language materials, but will be fully translated into Spanish. The moderator will follow a semi-structured moderator guide for the focus groups (see **Attachment 6D**) and consent form (see **Attachment 6E**). The guides address the following research objectives:

- What information about the HINTS program do participants:
 - find most relevant to his/her own life, if any?
 - consider important to them, their families or their community more generally?
 - think really encourage their interest and participation in HINTS 4?
- Are there possible differences between the English and Spanish speaking groups in what messages seem most relevant, important or encouraging?
- Do participants understand the specific language used in the proposed materials in the intended manner? If not, what is the source and impact of the confusion?
- Do participants view any of the content in the proposed materials negatively or think the content is likely to diminish participation in the survey? If so, why?
- Does the format or style of the letter affect the level to which participants read and attend to the content of the letters?

Data Analysis. Westat will analyze the data using qualitative analysis methods. Consistent themes occurring in the focus groups summaries addressing the research questions will guide the

development of the final survey letters, reminder postcard and Question & Answer information planned for HINTS 4 data collection.

Other Considerations. The focus group activities and materials outlined in this memo have been approved by Westat's IRB (see **Attachment 6F**) and is currently under review at NCI's IRB. Approval or exemption from both IRBs will be provided to OMB once received and prior to the initiation of any testing.

No personally identifying information (PII) will be retained. PII will be collected only as part of the recruitment process. 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 focus group research.

Respondent Burden and Costs. The table below displays the burden estimates for this data collection effort. We anticipate screening up to 80 individuals and retaining 40 to participate across both the English- and Spanish-language focus groups. Each focus group session will last up to 90 minutes. The total respondent burden for this effort is estimated to be 67 hours. This effort will account for less than 4 percent of the total burden hours (1800) granted in OMB No. 0925-0589 approved package.

Estimates of Hour Burden and Respondent Cost

Types of Respondents	Instrument	Maximum Number of Respondents	Frequency of Response	Estimated Burden (Min/Hours)	Annual Burden Hours
General Public	Screening Questionnaire (Attach 6A)	80	1	5/60 (0.083)	7
	Focus Group/Moderator Guide (Attach 6C and 6D)	40	1	90/60 (1.5)	60
Total		120			67

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

List of Attachments (Attached Below)

- 6B: Reminder Letter
- 6C: Test Materials - Letters, FAQs, and Alternative Facts
- 6E: Consent Form
- 6F: Westat IRB Approval

List of Attachments (Attached in a Separate File)

- 6A: Screening Questionnaire
- 6D: Moderator Guide

Attachment 6B: Reminder Letter

[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 focus group 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: XX

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

Directions and a map are enclosed.

Kindly allow enough time for travel as we would like to begin on time. There will be 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]



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Dear Sir or Madam:

You've been selected to take part in an important national survey sponsored by the U.S. Department of Health and Human Services, the Health Information National Trends Survey (HINTS).

HINTS has interviewed over 10,000 people since 2003. From those interviews we've learned that:

- The number of Americans using email to talk with a doctor or doctor's office doubled between 2003 and 2007.
- In the past several years, as health information becomes more available on-line, American's trust in the health information they get on-line has decreased.
- During the same time period, public trust in doctors as a source of health information increased.

By completing this questionnaire, you can help health professionals use HINTS to find out how you and other Americans get health information now and what needs done to make that information easier to find and understand.

We ask that each adult in this household complete a questionnaire and return it to us in the postage-paid envelope within the next two weeks. We've enclosed \$2 as a token of our appreciation for your participation. Of course, your participation is voluntary. You can keep the money even if you decide not to take part in the survey.

Westat, a research firm under contract with us, is administering the survey. Your answers will be kept confidential to the extent provided by law. More information about the study is provided on the other side of this letter. You can also go to www.HINTS.cancer.gov to find out more about HINTS.

Thank you in advance for your cooperation. If you have any questions about the study or you would like to request more questionnaires, please call Westat toll-free at 1-888-636-6540.

Sincerely,

A handwritten signature in blue ink that reads "Bradford W. Hesse".

Bradford W. Hesse, Ph.D.
HINTS Project Officer
Chief, Health Communication and Informatics
Research Branch
National Institutes of Health
U.S. Dept of Health and Human Services
www.HINTS.gov

Si prefiere recibir la encuesta en Español, por favor llame 1-888-636-6536.

Some Frequently Asked Questions about the Health Information National Trends Survey

Q: What is the study about? What kind of questions do you ask?

A: The study concerns health and how people receive health information. For example, we will ask how you usually get information about how to stay healthy, the sources of information you most trust, and how you might like to get such information in the future. We will also ask about your beliefs on what contributes to good health, how best to prevent cancer, your participation in various health-related activities, and related topics.

Q: Where can I find out more about HINTS?

A: If you have any questions about the study or you would like to request more questionnaires, please call Westat toll-free at 1-888-636-6540, or you can go to www.HINTS.gov

Q: How will the study results be used? What will be done with my information?

A: Findings will help the U.S. Department of Health and Human Services promote good health and prevent disease by determining ways of better communicating accurate health information to Americans.

Q: How did you get my address?

A: Your address was randomly selected from among all of the known home addresses in the nation. It was selected using scientific sampling methods.

Q: Why should I take part in this study? Do I have to do this?

A: Your participation is voluntary, and you may refuse to answer any questions or withdraw from the study at any time. However, your answers are very important to the success of this study and will represent thousands of others. Getting an answer from all the households chosen for the study is the best way to make sure the study results reflect the thoughts and opinions of all Americans.

Q: Will my answers to the survey be kept confidential?

A: Yes. Your answers cannot be connected to your name or any other information that could identify you or your household, to the extent provided by law.

Q: How long will it take to answer the questions?

A: About 20 to 30 minutes.

Q: Who is sponsoring the study? Is this study approved by the Federal Government?

A: The study is sponsored by the U.S. Department of Health and Human Services. The study has been approved by the Office of Management and Budget (OMB), the office that reviews all federally-sponsored surveys. The OMB approval number assigned to this study is 0925-0538.

Q: Who is Westat?

A: Westat is a research company located in Rockville, Maryland. Westat is conducting this survey under contract to the U.S. Department of Health and Human Services.

Attachment 6C – 2: Cover letter 2 and Frequently Asked Questions



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Dear Sir or Madam:

I'm writing to ask you to take part in a national survey sponsored by the U.S. Department of Health and Human Services. The Health Information National Trends Survey (HINTS) is how policy makers and researchers identify the information that Americans need and want to know about health.

For example, by answering the HINTS survey you can help identify:

- How people find out about food and drug recalls
- The number of Americans who use the internet as their main source of health information
- How people order and receive their prescriptions medicines

By completing this questionnaire, you can help to find ways to get you and all Americans the health information you need, when you need it.

We ask that each adult in this household complete a questionnaire and return it to us in the postage-paid envelope within the next two weeks. We've enclosed \$2 as a token of our appreciation for your participation. Of course, your participation is voluntary. You can keep the money even if you decide not to take part in the survey.

Westat, a research firm under contract with us, is administering the survey. Your answers will be kept confidential to the extent provided by law.

More information about the study is provided on the other side of this letter. You can also go to www.HINTS.cancer.gov to find out more about HINTS, or call Westat toll-free at 1-888-636-6540.

Thank you in advance for your cooperation.

Sincerely,

A handwritten signature in blue ink that reads "Bradford W. Hesse".

Bradford W. Hesse, Ph.D.
HINTS Project Officer
Chief, Health Communication and Informatics
Research Branch
National Institutes of Health
U.S. Dept of Health and Human Services

Visit the HINTS
website:

www.HINTS.cancer.gov

Si prefiere recibir la encuesta en Español, por favor llame 1-888-636-6536.

**Some Frequently Asked Questions
about the
Health Information National Trends Survey**

Q: What is the study about? What kind of questions do you ask?

A: The study concerns health and how people receive health information. For example, we will ask how you usually get information about how to stay healthy, the sources of information you most trust, and how you might like to get such information in the future. We will also ask about your beliefs on what contributes to good health, how best to prevent cancer, your participation in various health-related activities, and related topics.

Q: How will the study results be used? What will be done with my information?

A: Findings will help the U.S. Department of Health and Human Services promote good health and prevent disease by determining ways of better communicating accurate health information to Americans.

Q: How did you get my address?

A: Your address was randomly selected from among all of the known home addresses in the nation. It was selected using scientific sampling methods.

Q: Why should I take part in this study? Do I have to do this?

A: Your participation is voluntary, and you may refuse to answer any questions or withdraw from the study at any time. However, your answers represent thousands of others and are very important to the success of this study. Getting an answer from all the households chosen for the study is the best way to make sure the study results reflect the thoughts and opinions of all Americans.

Q: Will my answers to the survey be kept confidential?

A: Yes. Your answers cannot be connected to your name or any other information that could identify you or your household, to the extent provided by law.

Q: How long will it take to answer the questions?

A: About 20 to 30 minutes.

Q: Who is sponsoring the study? Is this study approved by the Federal Government?

A: The study is sponsored by the U.S. Department of Health and Human Services. The study has been approved by the Office of Management and Budget (OMB), the office that reviews all federally-sponsored surveys. The OMB approval number assigned to this study is XXXX-XXXX.

Q: Who is Westat?

A: Westat is a research company located in Rockville, Maryland. Westat is conducting this survey under contract to the U.S. Department of Health and Human Services.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Dear Resident:

Recently, the U.S. Department of Health and Human Services mailed two questionnaires to your household for the Health Information National Trends Survey (HINTS). As of today we have not received any completed questionnaires from your household.

HINTS has interviewed over 10,000 people since 2003. This year, HINTS is asking you to participate. As health care in America continues to change, we want you to tell us what health topics matter the most to you. Will the ways you communicate with your doctor's change? Can you get current information about medical treatments for you or a family member? Do you have concerns about your ability to take care of your own health needs? HINTS is a way for you to let the government know what people like you do when you need health care information.

We know your time is valuable, but your participation in the study is important to its success. To understand the health topics important to people today, HINTS needs to collect the current views and experiences of all the people we're trying to contact.

Whether or not you or anyone in your family has ever had health problems, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help us understand what health information you and other Americans want and what needs done to make that information easier to find and understand.

In the event that your questionnaires were misplaced, replacements are enclosed. If you have any questions, please call Westat toll free at 1-888-314-1133 or go to www.HINTS.cancer.gov.

Sincerely,

Bradford W. Hesse, Ph.D
HINTS Project Officer
Behavioral Research Program
National Cancer Institute

Si prefiere recibir la encuesta en Español, por favor llame 1-888-636-6536.



Dear Sir or Madam:

You've been selected to take part in this year's Health Information National Trends Survey (HINTS). Policy makers and researchers use HINTS to identify the information that Americans need and want to know about health. With your help, we can use HINTS to keep Americans better informed on the health issues important to them.

We recently mailed two HINTS questionnaires to your home. As of today we have not received any back from your address. We know your time is valuable. However, your household is part of a scientific sample representing many other households and it cannot be replaced.

To make sure HINTS provides accurate information we need you and all the household's selected for this year's HINTS to complete the survey. By taking part in this survey, you can help us find ways to get you and all Americans the health information you need, when you need it.

In the event that your questionnaires were misplaced, replacements are enclosed. **We ask that each adult in this household complete a questionnaire and return it to us in the postage-paid envelope within the next two weeks.**

If you have any questions or would like to request additional questionnaires, please call Westat toll free at 1-888-636-6540.

Sincerely,

Bradford W. Hesse, Ph.D.
HINTS Project Officer
Chief, Health Communication and Informatics
Research Branch
National Institutes of Health
U.S. Dept of Health and Human Services

To find out more about
HINTS, go to:
www.HINTS.cancer.gov

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Attachment 6C – 5: Alternative Facts

SET 1.

Using HINTS data, researchers and government officials can identify what types of information Americans need to correctly understand health risks. In 2005, HINTS found that:

- About 4 out of 5 adults believe that there are so many recommendations about nutrition that it is hard to know which ones to follow
- Similarly, more than three-quarters (78%) of Americans think there are so many cancer prevention recommendations that it is hard to know which ones to follow.

SET 2.

HINTS data can tell us what type of health information Americans are interested in. For example –

- Nearly 40% of all Americans have looked for cancer information at some point.
- About 50% of those people are looking for information about a specific type of cancer, but nearly 20% are looking for information about cancer symptoms, early detection or diagnosis.

SET 3.

HINTS data can help doctors and other health care professionals improve the communication they have with their patients.

- About 45% of English speaking households feel their doctors always explain things to them in a way they can understand.
- However, only a little more than 30% of Spanish-speaking households feel their doctors explain things to them in an understandable way.



Attachment 6E: CONSENT FORM

You have volunteered for a focus group discussion being conducted on behalf of the U.S. Dept. of Health and Human Services (DHHS). The purpose of the study is to improve certain procedures used for a survey that Westat conducts on behalf of DHHS.

- The discussion will be videotaped and notes will be taken. Project researchers may also observe the discussion.
- The discussion should take up to 1½ hours.
- Your participation is completely voluntary. You may stop at any time, and you do not have to answer any questions you do not wish to answer.
- This research does not involve any foreseeable risks.
- All information obtained from this study will be kept secure and will only be seen by people authorized to work on this project. The report summarizing the findings will not contain any names or identifying information. We will destroy any identifying information when the project ends.
- There are no direct benefits to participants in this research.
- Participants will receive \$50 in cash for participating.
- If you have questions about this research please contact Brad Hesse, the Principal Investigator at NCI (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 (800-937-8285; sharonzack@westat.com).
- A copy of this consent form has also been provided for your records.

If you agree to participate in this focus group, please read the following statement and sign your name below:

I have read the above information about this project and my rights as a participant. I consent to participate in this research and to have this discussion videotaped.

Researcher's Signature

Participant's Signature

Printed Name

Printed Name

Date

Attachment 6F: Westat IRB approval



An Employee-Owned
Research Corporation

Memo

Date: November 30, 2010
To: Terisa Davis, Project Director
From: Kerry Levin; Chair, Westat IRB
Subject: **Amendment Approval of OMB, 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: **OMB, Project 8861.01.04**. The Westat IRB reviews all studies involving research on human subjects. This project was last approved November 11, 2010.

This request was to approve the following:

1. Focus group research to elicit feedback on alternative message content included in the survey mailing materials.
2. Revise the informed consent form. Replace “confidential” to “secure.” As in: All information obtained from this study will be kept secure.
3. Decrease the incentive amount from \$75 to \$50.

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, 2011.
- 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