February 8, 2007

To: Seleda Perryman, HHS

FR: Sandra W. Hilfiker, ODPHP

RE: Request for Clearance of Individual Study re: OMB No. 0990-0281, Prevention

Communication Formative Research, Submission #6

Statement of Need

The Office of Disease Prevention and Health Promotion (ODPHP) seeks to create a prototype of an interactive digital health information resource to help Americans stay healthy. The prototype will consist of several sets of interactive health information (text content, links and interactive tools) pertaining to specific disease prevention and health promotion topics. In order to design an effective prototype, the navigation and display of this information must be tested for appropriateness, acceptability, applicability, motivation and engagement properties. The purpose of the research proposed here is to measure these properties with a low literacy/low health literacy audience and derive actionable recommendations to inform the requirements of the final prototype interactive digital health information resource.

Intended Use of Information

The information collected will be used to:

- 1. Provide an opportunity for potential users to interact with and provide feedback on a set of existing eHealth materials (text content, links, and interactive tools) related to the 25 most valuable clinical preventive services as recommended by the U.S. Preventive Services Task Force.
- 2. Determine which features of eHealth materials currently available from Federal government and partner organizations are found useful, engaging and effective by potential users.
- 3. Provide an empirical and customer-centered basis on which to make recommendations for the development of effective interactive eHealth tools.
- 4. Serve as a platform to tailor an ongoing evaluation plan for ODPHP to assess the extent to which prevention content on government web sites is meeting audiences' needs and affecting health outcomes.

The ODPHP contractor, Z-Tech Corporation, will conduct the study, summarize and interpret results, generate the resulting recommendations and tailor the on-going evaluation plan.

Description of Respondents

The respondents will consist of 43 adult women between 25 and 64 years of age, to reflect a) documented gender dominance in health-information seeking behaviors, and b) the age range of

current healthfinder.gov users. A diverse group of participants will be recruited, with emphasis on low literacy and low health literacy. All participants will be recruited in the Washington DC and/or Baltimore, MD area. All participants will take part in a one-on-one usability test session using a Web application. Three participants will be asked to pre-test the study protocol using the Web application. (Their data will not be included in the final analysis, but they will be remunerated.)

Research participants will be screened and recruited by an independent recruiting firm with a database of participants pre-segmented by gender, race/ethnicity, age, education and income.

Information Collection Procedures

Participants will be recruited and screened. The 40 respondents and 3 pre-test participants will be invited to come to a central location and spend an hour reviewing a clickable prototype Web application on a laptop computer. They will fill out a consent form and a demographic questionnaire, and respond to a set of engagement measures. All forms will be administered by the Web application (see attached instruments). Participants will be giving consent to having their usability test session audio- and video-taped. The consent form will also display the OMB Clearance number, expiration date, and burden disclosure statement.

The protocol for the usability test will be based on the industry standard usability task analysis method. Participants will be administered a series of six tasks to perform using the Web application. Typical examples of tasks include:

- Using this Web application, locate information on healthy eating.
- Find a tip or strategy you can use today to start exercising.
- Find information that will help you decide if you need to get your blood pressure checked.
- Print a page of information that you would like to discuss with your doctor.

As they complete the tasks, participants will be encouraged to verbalize their thoughts in reaction to the content and navigation of the Web application. Their facial expressions and comments will be captured on videotape for qualitative analysis. Quantitative analysis, in the form of summary statistics, will be performed on the following data collected by the Web application:

- Time to complete each task
- Number of clicks to complete each task
- Response to engagement measures
- Response to demographic questions

Incentive Justification

An incentive fee of \$75.00 will be offered to recruit participants for the research. Based on the experience of local market research firms, this sum is necessary to ensure that the required number of respondents fulfill their commitment to participate within the timeframe of the research study. ODPHP's contractor inquired about incentive payments with several recruiting

firms in the metropolitan D.C. area and was uniformly told that \$75 per participant is the standard and the minimum necessary to ensure that participants show up.

One recruitment firm offers the following evidence-based justification for this recommendation:

Several years ago, our Internal Revenue Service (IRS) customer agreed to let us compare the level of effort and success rate of recruiting for a usability test with an incentive of \$25 versus \$45 – both of which were low compared to industry standards. While it didn't take any more contacts or phone calls to get people to agree to participate for \$25 versus \$45, there were significantly more "no shows" for the group that had been promised \$25 than from the group that had been promised \$45. Even for the \$45 group there seemed to be more "no shows" than usual.

These "no shows" create significant risks to the budget and schedule associated with the study:

- Funds are wasted while research assistants who are ready to administer the study have no participants to test;
- Extra money must be spent to pay the research assistants to run the study with new participants;
- Rescheduling new participants pushes the schedule back, jeopardizing project goals; and
- Additional research facility fees may be incurred for each new participant scheduled.

To avoid these risks, ODPHP requests OMB approval to remunerate participants at the rate of \$75.00 per session.

Justification for Proposed Collection Methodology

This proposed study attempts to answer the following four research questions:

RQ1: Which precursors of behavior change are most positively affected by prevention information?

RQ 2: Are there existing prevention materials that do not meet the standards of appropriateness, acceptability, and applicability among consumers?

RQ 3: Which dimensions of engagement are most associated with indicators of behavior change?

RQ 4: Do dimensions of engagement predict user-rated acceptability and appropriateness of prevention information?

ODPHP seeks clearance for 43 respondents to ensure that enough data is gathered to be able to form actionable conclusions for the proposed use of the information collection.

Estimated Response Burden

The protocol is designed to take no more than 1 hour. Thus, the estimated number of hours anticipated for 43 research participants is about 43 hours.

The cumulative number of hours used under OMB No. 0990-0281 is 1053 hours.

Participant Screener

Attached.

Study Instrument

Attached. The questionnaires will be pre-tested to assure that all items are comprehensible to participants.

Participant Screener for Online Test Participants Under OMB No. 0990-0281, Prevention Communication Formative Research

Individuals will be asked the following questions and those who answer affirmatively to the responses denoted with the word "Accept" will be eligible to participate in the study:

| 1. | Hav | Have you participated in a usability study for a Web site in the last six months? | | | |
|----|-----|---|--|--|--|
| | 0 | Yes (Reject) | | | |
| | 0 | No (Accept) | | | |
| | | | | | |
| 2. | On | average, how often do you use the Internet? | | | |
| | 0 | Nearly every day (Reject) | | | |
| | 0 | A couple times a week (Accept) | | | |
| | 0 | About once a month (Accept) | | | |
| | 0 | A couple times a month (Accept) | | | |
| | 0 | Less than once a month (Accept) | | | |
| | 0 | I have never used the Internet (Reject) | | | |
| | | | | | |
| 3. | Wh | en was the last time you used the Internet to obtain health information? | | | |
| | 0 | In the past six months (Reject) | | | |
| | 0 | In the past 6 months to a year (Reject) | | | |
| | 0 | Over a year ago (Accept) | | | |
| | 0 | I have never used the Internet to obtain health information (Accept) | | | |
| | 0 | I have never used the Internet (Reject) | | | |
| | | | | | |

Study Instrument Under OMB No. 0990-0281, Prevention Communication Formative Research

ODPHP Task 5 Content Prototype Test

Overview of the protocol

The main purpose of the protocol is to ascertain whether the display formats for the health information conform to the informational needs of our target audience.

The objectives of the protocol are:

Determine which precursors of behavior change are most positively affected by prevention information.

Determine if there are existing prevention materials that do not meet the standards of appropriateness, acceptability, and applicability among consumers.

Determine which dimensions of engagement are most associated with indicators of behavior change.

Determine if dimensions of engagement predict user-rated acceptability and appropriateness of prevention information.

The protocol has two sections.

- Section 1 is designed to allow the participants to interact with and provide feedback on a set of eHealth materials (text content, links, and interactive tools) and respond to measures of appropriateness, acceptability, applicability, and engagement.
- Section 2 asks respondents to respond to demographic questions.

The protocol outline is as follows:

- 1. Section 1: review of content sets and Semantic differential scale questions (respondent administered)
- 2. Section 2: demographic questions (respondent administered)

This protocol is intended primarily to provide a structure for the session.

The content of the session will result primarily from the respondent's answers to closed-ended questions in the instrument, with one open-ended question at the end.

Section 1. Prototype Review

Before beginning the session, the respondent will read and sign the Informed Consent statement. The Research Assistant will read aloud the Introduction:

On behalf of the Office of Disease Prevention and Health Promotion (ODPHP), a division of the U.S. Department of Health and Human Services, Z-Tech Corporation is interviewing adults who use the Internet to look for health information.

The title of this research study is "Prevention Content for ODPHP Websites and Print Materials." The purpose of this exercise is to determine if the prevention information we've put together makes sense to you.

Usability Tasks

After reading the introduction, participants proceed to the first of six tasks that they will perform using the Web application. A dialog box will appear with task instructions. Participants click a button when they are ready to proceed. While they navigate the Web site, the task will be reinforced at the top of the computer screen. When they feel they have completed the task, they will click a button labeled "Done." A dialog box will appear with the next task.

Typical examples of tasks include:

- Using this Web application, locate information on healthy eating.
- Find a tip or strategy you can use today to start exercising.
- Find information that will help you decide if you need to get your blood pressure checked.
- Print a page of information that you would like to discuss with your doctor.

As they complete the tasks, participants will be encouraged to verbalize their thoughts in reaction to the content and navigation of the Web application.

Response to Engagement Measures

After completing all tasks, the Web application will present the participant with the engagement measures (see attached).

Section 2. Demographic Questions

After completing the engagement measures, the Web application will present the participant with a demographic questionnaire (see attached).

Participant Questionnaires – Response to Engagement Measures

OMB BURDEN STATEMENT: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0281. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

Engagement Measures, Part 1

Now that you have reviewed this Web site, please tell us how strongly you agree with these statements.

| | 1 | 2 | 3 | 4 | 5 |
|---|-------------------|-------|---------|----------|----------------------|
| This information: | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
| Was presented in ways that I could easily understand. | 0 | 0 | 0 | 0 | 0 |
| Was easy to use. | 0 | 0 | 0 | 0 | 0 |
| Was useful to me. | 0 | 0 | 0 | 0 | 0 |
| Is something I would recommend to a friend or relative. | 0 | 0 | 0 | 0 | 0 |
| Gave me some specific ideas about what to do. | 0 | 0 | 0 | 0 | 0 |
| Made me feel more confident that I can do something. | 0 | 0 | 0 | 0 | 0 |
| Made me feel more prepared to do something. | 0 | 0 | 0 | 0 | 0 |
| Made me feel more prepared to do something in the next month. | 0 | 0 | 0 | 0 | 0 |

Engagement Measures, Part 2

Please tell us how strongly you feel that each of these words describes the health information you just saw.

| | 1 | 2 | 3 | 4 | 5 |
|--------------------|----------|-------|---------|----------|----------|
| | Strongly | Agree | Neutral | Disagree | Strongly |
| | Agree | _ | _ | _ | Disagree |
| Absorbing | 0 | 0 | 0 | 0 | 0 |
| Attention-Grabbing | 0 | 0 | 0 | 0 | 0 |
| Stimulating | 0 | 0 | 0 | 0 | 0 |
| Surprising | 0 | 0 | 0 | 0 | 0 |
| Suspenseful | 0 | 0 | 0 | 0 | 0 |
| Thought-Provoking | 0 | 0 | 0 | 0 | 0 |
| Clever | 0 | 0 | 0 | 0 | 0 |
| Convincing | 0 | 0 | 0 | 0 | 0 |
| Balanced | 0 | 0 | 0 | 0 | 0 |
| Believable | 0 | 0 | 0 | 0 | 0 |
| Not Dull | 0 | 0 | 0 | 0 | 0 |
| Hip, Cool | 0 | 0 | 0 | 0 | 0 |

Open-Ended Question, Part 3

Any other comments?

Do you have any other comments about the health information you reviewed today? For example, the way it was presented or the kind of information that was presented.

Participant Questionnaire – Demographics

OMB BURDEN STATEMENT: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0281. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

Please tell us a little about yourself.

| 1. | How old are you today? | | | | | |
|----|---|--|--|--|--|--|
| | O 18-29 | | | | | |
| | O 25-49 | | | | | |
| | O 50-64 | | | | | |
| | | | | | | |
| 2. | What is your level of education? | | | | | |
| | O Some High School | | | | | |
| | O High School Graduate or GED Equivalent | | | | | |
| | O Some College | | | | | |
| | | | | | | |
| 3. | What was the total annual income of your household last year, before taxes? | | | | | |
| | O Less than \$20,000 | | | | | |
| | O \$20,000 to \$40,000 | | | | | |
| | O Over \$40,000 | | | | | |
| | | | | | | |