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**DATE:** February 22, 2010

**TO:** Seleda Perryman, HHS

**FROM:** Kathleen Loughrey, Health Communications Advisor, ODPHP

**RE:** Request for Clearance of Individual Study regarding OMB No. 0990-0281.  
Consumer Focus Groups for Messages and Guidance on the 2010 *Dietary Guidelines for Americans*, Submission #3

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### **Statement of Need**

In the fall of 2010, the United States Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) will release the 2010 *Dietary Guidelines for Americans (DGA)*. The Dietary Guidelines provide advice about eating a healthful diet by making food choices that can promote health and prevent disease; the guidelines are revised as necessary every five years based on the prevailing scientific evidence. The purpose of the proposed messages and consumer publication (print and/or electronic) is to generate understandable and actionable information to facilitate adoption of the Dietary Guidelines by consumers, particularly those with low health literacy. The goal is for Americans to become aware of and understand the specific aspects of the new guidelines and work towards meeting the guidelines, if they are not already doing so. HHS plans to conduct focus groups with audiences with limited health literacy to help translate the scientific findings contained in the new Dietary Guidelines into messages and guidance that is attractive, easy to understand and that includes useful tips on how to make healthy food choices. Focus group sessions will explore participants' beliefs, attitudes and behaviors with respect to healthy food choices and test potential messages that would be part of the consumer publication or tool (print and/or electronic).

### **Intended Use of Information**

The information collected will be used to:

- Learn about consumers' beliefs, attitudes and current behaviors related to food choices to design a consumer publication or tool (print and/or electronic) that provides information about the Dietary Guidelines that is relevant, clear, easy-to-understand, and actionable by the general adult public, including those with a low level of health literacy.

The American Institutes for Research (AIR) will conduct the focus groups, summarize and interpret results, and produce a report with recommendations for the development of a consumer publication or tool (print and/or electronic) booklet related to the 2010 *Dietary Guidelines for Americans*. Oversight for this research is provided by Kay Loughrey, Health Communications Advisor, ODPHP.

## Description of Participants

Participants in the focus groups will include adult men and women with limited health literacy levels who are not following a restricted diet due to a health condition and have not had bariatric surgery. All races and ethnicities will be eligible for participation. English should be their primary language. Participants will be between 25 and 64 years old.

The focus groups will be segmented by location and whether participants are “contemplating” or are “preparing” to make healthier food choices, as defined by the transtheoretical model of behavior change.<sup>1</sup> Individuals who are *not* meeting the Dietary Guidelines for fruits and vegetables consumption, but who are contemplating or planning to do so, will be separated from individuals who are already preparing to meet the guidelines. Those who are already meeting the guidelines and those who are not meeting them and are not contemplating doing so will be excluded. Participants will be segmented this way to find individuals who would be most likely to be responsive to communication products regarding the Dietary Guidelines.

A mix of participants – in gender, age and from different racial/ethnic backgrounds – will be invited to participate in the discussion groups. To ensure inclusion of individuals from the major racial/ethnic groups and geographically diverse locations, the focus groups will be conducted in: Baltimore, Maryland; Chicago, Illinois; and Jackson, Mississippi (Table 1).

**Table 1. Focus Group Segmentation**

Location	Stage of Change Regarding Fruit and Vegetable Consumption		
	Contemplating eating more fruits and vegetables	Preparing to eat more fruits and vegetables	Total
Baltimore, MD	1 group	1 group	2
Chicago, IL	1 group	1 group	2
Jackson, MS	1 group	1 group	2
Total	3 groups	3 groups	6 focus groups

The locations selected for the focus groups are in states characterized by different proportions of the population that are not meeting the Dietary Guidelines for fruit and vegetable consumption (Table 2). When divided into 3 groups (tertiles), Mississippi is in the lowest group for both fruit and vegetable consumption while Maryland is in the middle group for both fruit and vegetable consumption. Illinois is in the highest group for consumption of fruits and the middle group for vegetable consumption.

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<sup>1</sup> Weinstein ND, Rothman AJ, Sutton S (1988). Stage theories of health behavior: conceptual and methodological issues. *Health Psychol* 17: 290-299.

**Table 2. Population meeting the guidelines for fruit and vegetable consumption (percentage)**

State	Fruit Consumption	Vegetable Consumption
Mississippi	12.8%	7.2%
Illinois	26.5%	14.6%
Maryland	19.1%	12.9%

**Sources:** Agricultural Research Service (USDA). Human nutrition products and services; [http://ars.usda.gov/Services/docs.htm?docid=15763&pf=1&cg\\_id=0](http://ars.usda.gov/Services/docs.htm?docid=15763&pf=1&cg_id=0); last modified 7/31/2009  
[http://ars.usda.gov/Services/docs.htm?docid=15756&pf=1&cg\\_id=0](http://ars.usda.gov/Services/docs.htm?docid=15756&pf=1&cg_id=0); last modified 7/31/2009

**Notes:** Fruits- low: < 18.8%; middle: 18.8% to < 25.4%; high:= or > 25.4%  
Vegetables- low: < 13.5%; middle: 13.5% to < 15.7%; high:= or > 15.7%

### Information Collection Procedures

Professional recruiting services will be used to recruit and screen participants for the focus groups. Screening will be conducted over the telephone using lists of potentially eligible households. Recruiters may also work with adult education centers that provide literacy classes for English-speaking adults, to identify participants. Screening of potential focus group participants is estimated to take 10 minutes per respondent. We anticipate a recruitment rate of 20% and will screen 300 individuals to recruit 60 focus group participants (10 participants per focus group, resulting in 6 focus groups in total). Each of the six focus groups will consist of 10 participants and will last 2 hours (120 minutes). An incentive fee of \$75 will be offered to recruit participants for the focus groups.

The focus group discussions will take place at professional research facilities and will be moderated by a trained focus group moderator. Group discussions will be video-taped and audio-taped and may be transcribed for the purposes of analysis. A consent form including a confidentiality statement will be read to all participants. It will be written at an 8<sup>th</sup> grade reading level or less. Each participant will be asked to sign the consent form before the focus group begins. The consent form will display the OMB clearance number, expiration date, and burden disclosure statement, and will be printed using 14 point font to facilitate reading by participants, most of whom have a low literacy level.

The focus group moderators will use topic guides designed for this study based on the evidence available regarding aspects that can influence food decisions. The focus group discussion guide will test several concepts and cover the following topics:

- Identify 1 to 3 actionable messages that most interest respondents in terms of making healthier food/eating choices and addressing issues of weight management.
- Uncover key motivators and barriers to making healthier food/eating choices and addressing weight issues.
- Discover behavioral strategies for making weight management and healthier food selection personally attainable.
- Learn what actions respondents are already taking to make healthier food choices and manage their weight in terms of their current food behaviors (i.e. when shopping, preparing foods and eating out; obtaining support from friends and family).

- Identify how respondents make food decisions including portion sizes. Discover which visual approaches respondents would find most helpful for making decisions about food portions.
- Learn what information would help respondents get started/set goals in making healthier food choices and most favored ways to get this information, including sources of interpersonal support.
- Assess the understanding, relevance, and usefulness of food groups in participants' understanding of healthy eating.

Moderators will be trained in the use of the guides by the AIR project director. The guides will be reviewed and approved by the AIR Institutional Review Board (IRB) along with the consent forms and any other data collection materials. The topic guides will facilitate participation and ensure that data are collected as planned. Each focus group will last approximately 120 minutes. There will be 2 focus groups per location for a total of 6 focus groups.

Audio and video recordings and notes from the focus group discussions will be reviewed and analyzed to explore concepts, themes and reactions to messages with respect to the topics of interest, among participants at different stages of change regarding healthy eating (contemplation or preparation) with respect to the guidelines. AIR will prepare and submit a top line report describing the findings from the 6 focus group discussions including recommendations for messages, design and content of the consumer booklet.

Information that could be used to identify individual participants will not be provided to HHS and its agencies. No names will be associated with individuals' comments in the top line report. All information individually identifying regarding participants in the focus groups will be stored in a password-protected secure computer server at AIR. These files and the digital audiotapes and/or videotapes will be deleted one year after the end of the project, along with any printed participant lists used for the groups.

Copies of the focus group participant screener and focus group moderator's guide are appended to this packet.

**Table 3. Focus Group Description-Burden Hours**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>No. Of Respondents</b>	<b>No. of Responses</b>	<b>Average Burden Per Respondent</b>	<b>Total Burden Hours</b>
Consumer	Focus Group Participant Screener	300	1	10 minutes	50 hours
Consumer	Focus Group Moderator's Guide	60	1	120 minutes	120 hours
<b>Totals</b>					<b>170 hours</b>

## **Incentive Justification**

An incentive fee of **\$75** will be offered to recruit participants for the focus groups. This amount is consistent with previously submitted requests under this clearance and is necessary to ensure that the required number of participants fulfill their commitment to participate in the focus groups within the timeframe of the research study. If incentives of this amount are not offered, it will be difficult to secure a recruitment firm willing to collaborate and/or to secure individuals willing to participate. This would create significant risks that ODPHP will not get the information we seek, thereby compromising the integrity and quality of the study. The main problems are:

- Recruitment may take longer than anticipated and delay the development of the consumer publication or tool (print and/or electronic), which are required by the fall of 2010
- Research expenses for travel and data collection will be higher if the focus groups need to be rescheduled
- Additional focus group facility fees will be incurred, if any of the groups have to be rescheduled due to an insufficient number of participants

To avoid these risks, ODPHP requests OMB approval to remunerate participants at the rate of **\$75.00** per two-hour focus group session.

## **Justification for Proposed Collection Methodology**

The proposed study attempts to answer the following research questions through the conduct of focus group sessions with representatives of the target audience:

- RQ1: Which messages resonate most with consumers to increase awareness, understanding, and self-efficacy with respect to the revised Dietary Guidelines, among a diverse audience with limited health literacy?
- RQ2: What are the current practices with respect to healthy food choices, and the key motivators, barriers and behavioral strategies to making healthier food choices more attainable?
- RQ3: What content should be included and how should it be presented in a consumer booklet on the revised Dietary Guidelines for Americans for an audience with limited health literacy?

There will be a total of 6 groups conducted. At each location, there will be 2 focus group sessions. Each focus group will include 10 participants, for a total of 60 participants. The proposed number of participants and focus groups, and the duration of the focus groups will maximize the use of available resources to ensure that sufficient data is gathered to form actionable conclusions for the proposed use of the information collected.

As mentioned, the focus groups will be segmented by the stages of change (contemplation or preparation) with respect to consumption of fruits and vegetables as indicated in the upcoming Dietary Guidelines. A mix of participants of both genders with different racial/ethnic

backgrounds and varied ages between 25 and 64 years will be invited to participate. Focus groups will be conducted at different locations across the United States to include states with varying proportions of the population meeting the guidelines and ethnic diversity. Different geographical settings may affect healthy food choices.

### **Estimated Response Burden**

Screening of potential focus group participants is estimated to take 10 minutes per respondent. We estimate a 20% response rate and intend to screen 300 participants in order to recruit 60 to participate in the focus groups. So, the total estimated response burden for recruiting 60 participants is 50 hours.

### **ESTIMATED TOTAL BURDEN HOURS for Screening of Focus Group Participants = 50 hours**

The focus group sessions are designed to last 120 minutes each, for a total of 120 minutes per participant. Thus, the estimated response burden anticipated for 60 focus group research participants is 120 hours.

### **ESTIMATED TOTAL BURDEN HOURS for Focus Groups = 120 hours**

The cumulative number of hours used under OMB No. 0990-0281 is 373.

### **APPENDICES [IN SEPARATE FILES]**

1. Focus Group Participant Screener
2. Focus Group Moderator's Guide
3. Focus Group Consent Form