Supporting Statement for Request for Clearance:

Prevention Communication Formative Research

OMB No. 0990-0281

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SUPPORTING STATEMENT
PREVENTION COMMUNICATION FORMATIVE RESEARCH

This is a revision of an approved collection of information (OMB No. 0990-0281). According to OMB guidance regarding generic clearance, individual memos explaining the exact method for information collection will be submitted, as well as copies of the tools or instruments to be used in gathering the data.

Changes in this request include minor changes to data collection activities and related burden hours in order to meet the needs of the initiatives mentioned above. Average response time per data collection has also been amended based on recent experience with similar data collections. This request also places more emphasis on Web based data collection to allow greater geographical diversity among respondents, to decrease respondent burden, and to save government costs.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of Disease Prevention and Health Promotion (ODPHP), located in the Office of Public Health and Science at the U.S. Department of Health and Human Services (HHS), was established by Congress to provide a central focus for stimulating and coordinating Federal activities in prevention (Public Law 94-317, National Consumer Health Information and Health Promotion Act of 1976). This focus includes developing and disseminating prevention information to the public. Recent advances in information and communication technologies provide new opportunities for ODPHP to more effectively reach its intended consumer audiences and stakeholders with key information, interactive tools and recommendations about prevention, including the benefits of healthy eating and increased physical activity.

ODPHP's new opportunities occur against a backdrop of increasingly urgent interest in finding effective ways to communicate health information to America's diverse population. *Healthy People 2010* established the elimination of health disparities as a major goal for the nation. In 2002, the Institute of Medicine (IOM) published *Speaking of Health: Assessing Health Communication Strategies for Diverse Populations*, a report that stimulated interest in how best to harness communication theory and technologies to reduce health disparities. In 2004, a report from the Agency for Healthcare Research and Quality (AHRQ) entitled *Literacy and Health Outcomes*, coupled with a new IOM report, *Health Literacy: A Prescription to End Confusion*, focused public attention on the role of health literacy in influencing health disparities. In September, 2006 Acting Surgeon General Kenneth Moritsugu held a Surgeon General's Workshop on Improving Health Literacy where participants identified the public health consequences of limited health literacy and established an evidence base for taking action.

As a federal government agency, ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels, from print through new communication technologies. To carry out its prevention information mandate, ODPHP is committed to conducting formative communication research to provide guidance to the development and implementation of its disease prevention and health promotion communication and education efforts. This generic clearance request describes data collection activities involving a limited set of focus groups, individual interviews, Web-based concept and prototype testing, and usability and effects testing to establish a deeper understanding of the interests and needs of consumers and health intermediaries for disease prevention and health promotion information and tools.

2. Purpose and Use of Information Collection

This generic clearance request describes data collection activities by ODPHP and its Contractors involving a limited set of research activities with consumers and intermediaries and about how they receive, process, and comprehend messages about prevention topics, guidelines, and initiatives. ODPHP staff will use the information collected to plan and/or approve strategies to better inform the public and ODPHP stakeholders about disease prevention and health promotion information and activities. ODPHP communicates through channels such as www.healthfinder.gov, online collaborative workspaces, and through more traditional channels such as print brochures and reports. ODPHP will also make recommendations to other agencies within HHS about how to effectively present disease prevention and health promotion information to the public. For example, formative research among audiences with limited health literacy may be used to guide the development of effective prevention information and Web pages developed by individual agencies within HHS. Another example may involve focus groups and interviews with special populations to target messages and materials related to the Physical Activity and Dietary Guidelines to encourage behavior change.

The primary methods of data collection will be qualitative and may include focus groups, and/or individual in-depth interviews on the public's understanding of prevention content, responses to prototype materials, and barriers to effective use. In addition, Web message concept testing and usability and effects testing of prototype materials at various developmental stages may be conducted. The use of individual interviews, focus groups, Web concept testing, and usability and effects testing as qualitative research has four major purposes:

- To obtain useful consumer information for the formation of messages and materials;
- To further explore messages and materials in contexts that would be most beneficial for consumers;
- To identify and verify audience segmentation strategies for providing prevention information; and
- To inform the development of user-friendly Web sites and other Web-based tools.

Both individual interviews and focus groups provide an important role in gathering information because they allow for more in-depth discussion and understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Web-concept testing surveys provide a cost-efficient method to obtain qualitative input from a greater number of participants who are more representative of the U.S. population across the country. Usability and effects testing is a cost effective, qualitative method to assess the strengths and weaknesses of interactive prevention materials.

3. Use of Improved Information Technology and Burden Reduction

Individual interviews and focus groups do not produce quantitative data, but instead data that enable skilled researchers to infer the underlying views and assumptions of the research participants~~the consumer.~~ To facilitate interpretation, discussions are recorded so that written transcripts of the interviews are available for review.

The Web-based concept-testing may be conducted among visitors to www.healthfinder.gov, or through an already existing Web panel maintained by a commercial vendor or an online panel recruited for this project. If a commercial vendor is used, participants will be randomly selected from the pool of potential participants retained by the research group. This method provides a cost efficient way to get input from a more diverse cross section of the U.S. population. This methodology will be particularly helpful to ascertain potential regional differences within special populations and intermediaries when respondents are asked to review prototype concepts for materials related to the Dietary Guidelines, Physical Activity Guidelines, and Healthy People 2020.

Usability testing of prototype concepts is typically conducted on a very small number of respondents, usually around eight people per round. Multiple rounds are usually conducted, as the concept is revised in response to the previous round. A skilled interviewer observes the respondent navigating through material, typically a Web site, often in response to specific commands from the interviewer (e.g., "please find information on this site about fruits and vegetables."). How the respondent works his or her way through the material to obtain the desired information is recorded by video for further review. An in-depth interview with the respondent about his or her experience and evaluation of the content typically follows the usability test in order to understand not only what occurred during the test, but how it felt subjectively from the respondent's perspective.

4. Efforts to Identify Duplication and Use of Similar Information

It is not expected that any of the information to be submitted to ODPHP during these formative research studies is duplicative or is already in the possession of the Federal Government. The proposed generic research will allow ODPHP to significantly improve its ability to develop and refine messages and materials that will be used by multiple agencies within HHS.

5. Impact on Small Businesses or Other Small Entities

Not Applicable.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, ODPHP's ability to effectively communicate disease prevention and health promotion information to the American public will be compromised. Relatively little is currently known, for example, about how to present messages in ways that can maximize how individuals with low health literacy can easily access and comprehend vitally important information about how to protect and promote their health. In addition, the emergence of new technologies requires that we do prototype testing in order to ensure that technology-based information and tools are easy for the public to use.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Various data collection activities may be conducted under the auspices of this request. Each activity is anticipated to be a one-time collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register notice was published in the Federal Register on May 16, 2008, Vol. 73, No. 96**.**

This revision was also reviewed by:
Linda Harris, PhD, Health Communication & eHealth Team Lead, Office of Disease Prevention and Health Promotion, HHS

9. Explanation of Any Payment or Gift to Respondent

A cash stipend intended to reimburse for expenses such as transportation and childcare costs will be given to research participants. For the general public, stipends will range from $50-$100 depending on the length of the study. For professionals, stipends will range from $75-$150 depending on the type of professional and length of the study. Specific a~~A~~mounts and justifications will be determined on an individual project basis. This information will be included in the memo provided to OMB for each formative input session to be conducted.

10. Assurance of Confidentiality Provided to Respondents

ODPHP and Contractors will follow procedures for assuring and maintaining privacy during all stages of data collection. Respondents will receive information about privacy in an advance letter and again before the information collection sessions begin.

Respondents will be informed that all information will be kept private to the extent allowed by law.

Respondents in focus group sessions will not know each other and will be asked to introduce themselves by first name only. The focus group sessions will be in a room with a closed door so passers-by cannot eavesdrop on the discussion. Focus group sessions will be timed to allow more than enough time between sessions to avoid respondents in different groups seeing each other. Individual interviews, usability, and Web concept testing will be conducted in a private setting.

At the beginning of focus group, individual interview, prototype testing, usability testing sessions, the facilitator will explain that the respondents' names and addresses will never be associated with the formative input session results.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

A. Burden Hours (chart here)

The total annual estimated burden imposed by this collection of information is 1,400 hours for a total of 4,200 total hours over a three-year period.

Data Collection Task	**Instrument/ Form Name**	**# of Respondents**	**# Responses/ respondent**	**Average burden/ response (in hours)**	**Total response burden (in hours)**
In depth interviews (Limited Literacy Consumers)	Screener	133	1	10/60	22.2
	Interview	33	1	1.5	50
	Confidentiality Agreement	33	1	5/60	2.8
In depth Interviews (Health Intermediaries)	Screener	75	1	10/60	12.5
	Interview	25	1	1.5	37.5
	Confidentiality Agreement	25	1	5/60	2.1
In depth Interviews (Public Health Professionals)	Screener	50	1	10/60	8.3
	Interview	25	1	1.5	37.5
	Confidentiality Agreement	25	1	5/60	2.1
In person Focus Groups (35)-- Limited Literacy Consumers	Screener	372	1	10/60	62
	Focus Group	93	1	2	186
	Confidentiality Agreement	93	1	5/60	7.75

Data Collection Task	Instrument/ Form Name	# of Respondents	# Responses/ respondent	Average burden/ response (in hours)	Total response burden (in hours)
In Person Focus Groups (20)-- Health Intermediaries	Screener	159	1	10/60	26.5
	Focus Group	53	1	2	106
	Confidentiality Agreement	53	1	5/60	4.4
In person Focus Groups (15)-- Public Health Professionals	Screener	80	1	10/60	13.3
	Focus Group	40	1	2	80
	Confidentiality Agreement	40	1	5/60	3.3
Usability and other testing of prototype materials (print and Web)	Screener	400	1	10/60	66.7
	Usability Test	100	1	1.5	150
	Confidentiality Agreement	100	1	5/60	8.3
Web-based concept and prototype testing	Screener	0	1	0	0
	Web-test	167	1	1	167
	Confidentiality Agreement	167	1	5/60	13.9
In person message testing	Screener	200	1	10/60	33.3
	Message Test	50	1	1	50
	Confidentiality Agreement	50	1	5/60	4.2
Telephone-based message testing	Screener	268	1	10/60	44.7
	Telephone Test	67	1	1	67
	Confidentiality Agreement	67	1	5/60	5.6
Web-based message testing	Screener	0	1	10/60	0
	Web-test	115	1	1	115
	Confidentiality Agreement	115	1	5/60	9.6
				TOTAL	**1,400**

B. Burden Cost (average hourly rate)

Data Collection Task	Instrument/ Form Name	Response burden (in hours)	Hourly Wage Rate	Respondent Cost
Individual interviews (Limited	Screener	22.2	$19.29	$428.24
	Interview	50	$19.29	$964.50

Data Collection Task	Instrument/ Form Name	Response burden (in hours)	Hourly Wage Rate	Respondent Cost
Literacy Consumers)	Confidentiality Agreement	2.8	$19.29	$54.01
Individual Interviews (Health Intermediaries)	Screener	12.5	$19.29	$241.13
	Interview	37.5	$19.29	$723.38
	Confidentiality Agreement	2.1	$19.29	$40.51
Individual Interviews (Public Health Professionals)	Screener	8.3	$19.29	$160.11
	Interview	37.5	$19.29	$723.38
	Confidentiality Agreement	2.1	$19.29	$40.51
In person Focus Groups (35)--Limited Literacy Consumers	Screener	62	$19.29	$1,195.98
	Focus Group	186	$19.29	$3,587.94
	Confidentiality Agreement	7.75	$19.29	$149.50
In Person Focus Groups (20)--Health Intermediaries	Screener	26.5	$19.29	$511.19
	Focus Group	106	$19.29	$2,044.74
	Confidentiality Agreement	4.4	$19.29	$84.88
In person Focus Groups (15)--Public Health Professionals	Screener	13.3	$19.29	$256.56
	Focus Group	80	$19.29	$1,543.20
	Confidentiality Agreement	3.3	$19.29	$63.66
Usability and other testing of prototype materials (print and Web)	Screener	66.7	$19.29	$1,286.64
	Usability Test	150	$19.29	$2,893.50
	Confidentiality Agreement	8.3	$19.29	$160.11
Web-based concept and prototype testing	Screener	0	0	0
	Web-test	167	$19.29	$3,221.43
	Confidentiality Agreement	13.9	$19.29	$268.13
In person message testing	Screener	33.3	$19.29	$642.36
	Message Test	50	$19.29	$964.50
	Confidentiality Agreement	4.2	$19.29	$81.02
Telephone-based message testing	Screener	44.7	$19.29	$862.26
	Telephone Test	67	$19.29	$1,292.43
	Confidentiality Agreement	5.6	$19.29	$108.02
Web-based	Screener	0	0	0

Data Collection Task	Instrument/ Form Name	Response burden (in hours)	Hourly Wage Rate	Respondent Cost
message testing	Web-test	115	$19.29	$2,218.35
	Confidentiality Agreement	9.6	$19.29	$185.18
			TOTAL	**$14,163.68**

$19.29 hourly rate is derived from the U.S. Department of Labor, Bureau of Labor Statistics June 2007 report—National Compensation Survey: Occupational Wages in the United States, June 2006. See http://www.bls.gov/ncs/ocs/home.htm#tables.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no new annual capital or maintenance costs to the respondent as a result of this data collection.

14. Annualized Cost to the Government

ODPHP will incur the following estimated costs annually in setting up testing environments and collecting and summarizing data:

- Developing study protocols: $40,000
- Developing study stimulus materials: $10,000
- Moderators and usability experts to conduct research: $10,000
- Study participant recruitment: $15,000
- Meeting space for data collection: $10,000
- Study participant stipends: $10,000
- Data summary and reports: $80,000

Estimated Annualized Cost to Government**: $175,000**

15. Explanation for Program Changes or Adjustments

ODPHP is proposing the following program changes:

1. Types of focus groups and interviews were consolidated to include three target audiences: those with limited literacy, health intermediaries (such as librarians and senior center staff), and public health professionals (such as health department staff and nurses). These are priority audiences for ODPHP.
2. Number of participants and therefore burden hours were added to several tasks including Web-based testing due to the growing demand for online information and tools. ODPHP is placing more emphasis on online communication and tools in our programs.
3. Web-based and telephone-based message testing were added as data collection tasks to enable ODPHP to get more geographically diverse samples and to reduce government costs.

4. Number of respondents and burden hours for screening participants was reduced across the board as our experience over the last 3 years demonstrated that we had overestimated this burden in the past.
5. Estimated hourly rate of respondents increased due to cost of living increases.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results for this information collection.

No complex or analytical techniques will be used for the results of the collection of information. Findings from all data collection will be included in individual summary reports submitted to ODPHP. The reports will describe the in-depth interview and/or usability testing methods, findings, conclusions, implications, and recommendations for use in development of disease prevention and health promotion messages, materials, and tools. There will be no specific quantitative analysis of data. No attempt will be made to generalize the findings to be nationally representative.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption is not requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

The data encompassed by the projects discussed in this supporting statement will fully comply with all guidelines of 5 CFR 1320.9 and no exception is requested to certification for Paperwork Reduction Act Submission.

B~~A~~. Collection of Information Employing Statistical Methods

Due to the nature of the research proposed, i~~I~~nformation will not be collected requiring statistical analysis employing statistical methods.~~.~~

1. **Respondent Universe and Sampling Methods**

A large majority of research proposed in this clearance request will utilize a convenience sample. ODPHP will partner with community organizations and other healthcare organizations to recruit a sample that meets the demographic characteristics we are interested in. The other method that will be used for recruiting participants is hiring a recruitment firm that will recruit participants from their databases that meet our criteria.

2. **Procedures for the Collection of Information**

Information will not be collected requiring statistical analysis employing statistical methods.

3. Methods to Maximize Response Rates and Deal with Nonresponse

ODPHP will not conduct mail or phone based surveys which cuts down on nonresponse issues. As mentioned above, a majority of the research will be done with a convenience sample, and participants will be remunerated to cut down on no shows. In the past we have had a very low 'no show' rate of 10% on average.

4. Tests of Procedures of Methods to be Undertaken

ODPHP often pre-tests focus group, interview, and survey questions with less than 10 people to make sure the questions and concepts are understandable. These pre-tests are done before ODPHP submits the memo to OMB for each formative input session.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

ODPHP uses a number of contracting firms to conduct formative research. Contractors are chosen for research projects on a competitive basis. Specific names and contact information of contractors who will design, collect, and analyze data will be included in the memo provided to OMB for each formative input session to be conducted.

ATTACHMENTS

A. 60-day Federal Register Notice

B. OMB Burden Statement