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 methods for information collection will be submitted for each study under this clearance.

Changes in this request include updating the national hourly wage and data collection activities and related burden hours. This request builds on previous formative research approaches to place 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) is located in the Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS). ODPHP 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, Section 207, Section 7). Our office focuses on 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 professional and consumer audiences with key information, interactive tools and recommendations about disease prevention, and health promotion, including the benefits of healthy eating, increased physical activity, and patient safety.

New opportunities for ODPHP occur against a backdrop of increasingly urgent interest in finding effective ways to communicate health information to America's diverse population. 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 to new communication technologies. To carry out this mandate, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of communication and education efforts. This generic clearance request describes data collection activities involving methods such as: individual interviews, focus groups, web-based surveys, card sorting and various forms of usability testing to establish a deeper understanding of the interests and needs of consumers and health professionals for disease prevention and health promotion information and tools.

2. Purpose and Use of Information Collection

This generic clearance request is for a revision to the use of the approved information collection assigned OMB control number 0990-0281. The request describes data

collection activities involving a limited set of research activities with consumers and health professionals to better understand their needs and preferences related to disease prevention, health promotion, and women's health products and initiatives. Specific to ODPHP, the office will use the information collected to improve its communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, healthfinder.gov, and increasing health care quality and patient safety. ODPHP communicates through its websites (www.healthfinder.gov, www.HealthyPeople.gov, www.health.gov) and through other channels including social media, print materials, interactive training modules, and reports.

Data collection methods will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public's understanding of disease health content, responses to prototype materials, and barriers to effective use.

The research methods outlined in this supporting statement have five major purposes:

1. To obtain useful target audience information for the formation of messages and materials
2. To further explore messages and materials in contexts that would be most beneficial for target audiences
3. To identify and verify audience segmentation strategies for providing health information
4. To inform the development and refinement of user-friendly websites and other interactive tools
5. To identify user challenges and obstacles to accessing health information to guide website, material, and interactive tool development and refinement

3. Use of Improved Information Technology and Burden Reduction

Remote, web-based testing is a cost-efficient method to obtain quantitative and qualitative input from a greater number of participants who are more representative of the U.S. population. Below is a description of how ODPHP will use technology, when possible, to reduce response burden.

Interviews and focus groups are recorded so that written transcripts of the interviews are available for review. Remote interviews and focus groups may be conducted by telephone or through web conferencing software.

Web-based surveys may be conducted among visitors to HealthyPeople.gov, healthfinder.gov, health.gov, or through an already existing survey tool (e.g., Qualtrics).

Online and omnibus surveys may be conducted remotely and online through a survey tool such as Qualtrics or Survey Monkey.

Card sorting is a common method for gaining insights from participants on how to effectively organize a website or online application. In-person card sorting is typically conducted in a one-on-one interview setting with a moderator and note taker. Web-based card sorting allows participants to use a "drag-and-drop" online interface to perform an un-moderated card sort on their own time.

Usability testing can be conducted either in person or remotely using Web conferencing software. The participant's screen and voice are typically recorded during both in-person and remote sessions so they can be reviewed later for reporting purposes. Usability testing also includes online methods such as tree testing and click testing.

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 their ability to develop and refine messages, materials, websites, and interactive tools 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, the ability of ODPHP to effectively communicate health information to the American public will be compromised. For example, relatively little is currently known 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 agencies conduct prototype testing in order to ensure that technology-based information and tools are easy for the public to use. There are no legal obstacles to reduce the burden.

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. This request fully complies with regulations.

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 September 29, 2017, Volume 82, Number 188, pp. 45600-45601. A number of comments were received from the Academy of Nutrition and Dietetics. Please see comments and ODPHP

responses as follows. The full letter from the Academy of Nutrition and Dietetics was submitted directly to Sherrette Funn on November 28, 2017.

i. The necessity and utility of the proposed information collection for the proper performance of the agency's functions

Academy of Nutrition and Dietetics Comments
The broad variety of proposed collection methods seems appropriate, and we recommend that ODPHP include evaluation methods completed by both consumers and health professionals to further enrich the data collection.

The Academy recommends that ODPHP collaborate across federal agencies when developing communication and education materials for the public. The proposal does not include information on any interagency initiatives, such as partnering with the Centers for Disease Control and Prevention or the Center for Nutrition Policy and Promotion, which do education for the public and have materials that require evaluation. A collaborative approach could help reduce replication of efforts and increase the utility of the data collection.

The Academy also recommends that ODPHP utilize the Academy's Evidence Analysis Library (EAL)[2] to identify existing research and any gaps in nutrition research. The EAL contains research on various nutrition and health projects through systematic reviews that look at the effectiveness of interventions on specific disease states. The Academy would be pleased to partner with ODPHP to reduce duplication of data collection efforts.

ODPHP Response
ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of our communication and education efforts. This generic clearance is intended to cover broad research activities across projects in ODPHP. Individual research project proposals that require OMB approval will include additional details regarding purpose of the research, intended audience, data collection methods, and estimated public burden.

We are in full agreement with your assessment of the importance of testing our products and plans with both health professionals and consumer audiences. Our generic clearance request describes data collection activities involving methods such as: individual interviews, focus groups, web-based surveys, card sorting and various forms of usability testing to establish a deeper understanding of the interests and needs of both consumers and health professionals for disease prevention and health promotion information and tools. We also agree about the need to collaborate across federal agencies when developing communication and education materials for the public. ODPHP's efforts are especially cross-cutting and require ongoing partnerships across HHS and other federal agencies. For example, Healthy People 2020 is managed by a Federal Interagency Workgroup,

with representatives from across the federal government, including HHS, Department of Veterans Affairs, Department of Education, and the Environmental Protection Agency, among others. The Dietary Guidelines is managed by both HHS and USDA.

ii. The accuracy of the estimated burden

Academy of Nutrition and Dietetics Comments
When reviewing the estimated burden in the proposed information collection, the Academy seeks clarification of the estimated burden for both the participant and the research team. For the participant, the Academy recommends that the burden include travel time to focus groups, time for child care, and other related time constraints. For the researchers, the Academy recommends including time for preparation and analysis both prior to and following the data collection. Additionally, focus groups may run longer or shorter than the proposed time, and often it is best to overestimate in these calculations in order to leave time for continuing meaningful interviews to capture rich data.

ODPHP Response
We seek to minimize the burden of our formative research activities on the public. OMB defines burden as "time, effort, or financial resources" the public expends to provide information to or for a Federal agency, or otherwise fulfill statutory or regulatory requirements. This includes: reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. Please find reference to the burden guidelines here: 44 U.S.C. 3502(2); 5 C.F.R. 1320.3(b).

iii. Ways to enhance the quality, utility and clarity of the information to be collected

Academy of Nutrition and Dietetics Comments
The Academy recommends more of a focus on diversity and reducing health inequities in the interview questionnaires. We were concerned by the lack of prioritization for populations with limited English proficiency, disabilities and variety of race and ethnic groups. It is important that the data collection account for specific populations, which are more heavily burdened by health inequities. Identifying appropriate ways to target communications based on diverse factors while working to overcome health inequities should be critical to this process.

It would also be helpful to describe the specific target population, as the current “consumers or health professionals” is a vague description. For example, ODPHP should identify specific populations that are the target of a communication initiative, based on factors such as specific geographic locations, age groups, genders, disease states or languages spoken.

ODPHP Response
We recognize the importance of obtaining feedback on our materials and products from a diverse group of stakeholders. 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 to new communication technologies. Each research proposal that is submitted under this generic clearance will outline the specific audience of the research activity, including those with limited English proficiency and those with low health literacy.

iv. The use of automated collection techniques or other forms of information technology to minimize the information collection burden

Academy of Nutrition and Dietetics Comments
The Academy recommends that ODPHP consider the feasibility and utility of web or phone based apps and/or text messages for gathering data.

ODPHP Response
Our generic clearance proposal includes the use of remote, web-based testing as a cost-efficient method to obtain quantitative and qualitative input from a greater number of participants who are more representative of the U.S. population. Where possible, ODPHP will use technology to reduce response burden, including remote interviews and focus groups, web-based surveys, web-based card sorting technology, and remote usability testing.

This revision was also reviewed by: Frances Bevington, MA, Strategic Communication and Public Affairs Advisor, Office of Disease Prevention and Health Promotion, HHS. Ms. Bevington supported the recommended revisions and did not have any additional comments.

9. Explanation of Any Payment or Gift to Respondent

Participants will be offered a cash incentive for the time they spent engaged in formative research activities. Amounts 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. Information Regarding Confidentiality Provided to Respondents

ODPHP and its contractors will follow procedures for assuring and maintaining privacy to the extent allowed by law 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 by the research team and that comments will not be associated with their names. There will be no promise of total and absolute confidentiality for individually identifiable information unless there is a firm legal basis for withholding information in the face of a

subpoena or court order or other Federal, State, or Local legislation.

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 passersby cannot overhear the discussion. In-person research sessions will be scheduled to allow more than enough time between sessions to avoid respondents in different groups seeing each other. All in-person testing will be conducted in a private setting.

At the beginning of each testing session, the facilitator will explain that the respondents' names and addresses will not 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

The total annual estimated burden imposed by this collection of information is 9,975 hours over a 3-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	Screener	1,500	1	10/60	250
	Interview	500	1	1.00	500
Focus groups	Screener	2,925	1	10/60	487.5
	Focus Group	975	1	1.50	1,462.5
Intercept interviews	Interview	5,250	1	5/60	437.50
Cognitive testing of instruments	Screener	150	1	10/60	25
	Cognitive Test	50	1	2.00	100
Web-based surveys	Screener	30,000	1	5/60	2,500
	Survey	10,000	1	15/60	2,500
Omnibus surveys	Survey	2,100	1	10/60	350
Gatekeeper reviews	Review	325	1	30/60	162.5
Card sorting	Screener	600	1	10/60	100
	Card Sort	200	1	1.00	200

Usability and prototype testing of materials (print and web)	Screener	1,800	1	10/60	300
	Usability Test	600	1	1.00	600
TOTAL					9,975.00

B. Burden Cost (average hourly rate)

Data Collection Task	**Instrument/ Form Name**	**Response Burden (in hours)**	**Hourly Wage Rate**	**Respondent Cost**
In-depth interviews	Screener	250	$23.86	$5,965.00
	Interview	500	$23.86	$11,930.00
Focus groups	Screener	487.5	$23.86	$11,631.75
	Focus Group	1,462.5	$23.86	$34,895.25
Intercept interviews	Interview	437.50	$23.86	$10,438.75
Cognitive testing of instruments	Screener	25	$23.86	$596.50
	Cognitive Test	100	$23.86	$2,386.00
Web-based surveys	Screener	2,500	$23.86	$59,650.00
	Survey	2,500	$23.86	$59,650.00
Omnibus surveys	Survey	350	$23.86	$8,351.00
Gatekeeper reviews	Review	162.5	$23.86	$3,877.25
Card sorting	Screener	100	$23.86	$2,386.00
	Card Sort	200	$23.86	$4,772.00
Usability and prototype testing of materials (print and web)	Screener	300	$23.86	$7,158.00
	Usability Test	600	$23.86	$14,316.00
TOTAL				$238,003.50

The $23.86 rate is derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2016 report "National Occupational Employment and Wage Estimates United States"[1]. The estimated annualized annual cost for this information collection for 9,975 hours of reporting time is $238,003.50.

The number of respondents and length of response was determined on the basis of other HHS agency's prior experience with communications testing and an estimate of the market research needs. The actual numbers will vary depending upon the topic of interest.

[1] See https://www.bls.gov/oes/current/oes_nat.htm.

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

- Developing study protocols: $60,000
- Developing study stimulus materials: $10,000
- Moderators and usability experts to conduct research: $20,000
- Study participant recruitment: $15,000
- Meeting space for data collection: $7,000
- Study participant stipends: $3,000
- Data summary and reports: $100,000

Estimated Annualized Cost to Government**: $215,000**

15. Explanation for Program Changes or Adjustments

ODPHP is proposing the following program changes:

1. Revise purpose and justification to reflect office initiatives and priorities for the next 3 years.
2. Add intercept interviews, cognitive testing, omnibus surveys, and gatekeeper reviews as research methods to understand user characteristics, needs, and preferences.
3. Increase total burden hours to reflect upcoming formative research needs.
4. Increase estimated hourly rate of respondents 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. The reports will describe the testing methods, findings, conclusions, implications, and recommendations for use in development and refinement 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. No exception is requested to certification for Paperwork Reduction Act Submission.

B. Collection of Information Employing Statistical Methods

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

APPENDICES

A. OMB Burden Hours Statement

B. Collection of Information Employing Statistical Methods