Supporting Statement A for:

Testing successful health communications surrounding aging-related issues

From the National Institute on Aging (NIA)

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Megan J. Homer, M.A.

Office of Communications and Public Liaison

National Institute on Aging

9000 Rockville Pike

Bldg 31C, Suite 5C27

Bethesda, MD 20892

Telephone: 301-496-1752

Fax: 301-496-1072

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**A.1 Circumstances Making the Collection of Information Necessary**

The National Institute on Aging (NIA), part of the National Institutes of Health (NIH) was established to improve the health and well being of older people through research.  NIA’s activities are authorized under 42 USC 285e, where it is stated, “The general purpose of the National Institute on Aging is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.” Based on this US Code, NIA established its mission: 1) to support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans; 2) to foster the development of research and clinician scientists in aging; 3) to communicate information about aging and advances in research on aging to the scientific community, health care providers, and the public.

The third component of NIA’s mission—health information dissemination—is primarily carried out by NIA’s Office of Communications and Public Liaison (OCPL). OCPL is responsible for (1) writing/designing health and aging information materials (including publications and content for websites) for older adults, caregivers, and health professionals and (2) conducting activities to raise awareness of these materials among those in need of this health and aging information.

Most NIA materials are “evidence-informed.” The topics are chosen based on what NIA OCPL observes as the needs of its audiences and based on the latest research conducted by the National Institute on Aging and other institutes at the National Institutes of Health. The presentation of the information is based on secondary research on the layout/format preferences of older people, where it exists. Health information can be particularly difficult to understand and act upon, even for the most capable person. There are some special considerations when developing written materials for older people. Alterations to learning and memory may affect an older reader’s ability to absorb content, and the way information is presented may need to accommodate the cognitive and physical changes that often accompany old age.

NIA OCPL believes it can better meet NIA’s communications mission by developing *evidence-based* materials. Developing evidence-based materials requires OCPL to conduct primary research with older adults, caregivers, health professionals and others who work with older people to determine what health and aging topics are of interest and not represented by NIA’s current materials. OCPL must also work directly with these audiences to determine the most effective presentation of NIA’s health information.

Along with producing health information materials, NIA’s OCPL is responsible for outreach to raise awareness of its free health and aging information resources among older people, caregivers, health professionals, and other groups and individuals working with or caring for older people. NIA’s outreach program is comprised of several activities that include a general NIA e-alert list with 2,000 participants who receive regular emails about new NIA publications and other activities; an Alzheimer’s disease (AD) NIA e-alert list with 11,000 participants who receive regular communications about NIA’s AD-related research and resources; three exhibit booths (each with a different audience focus) used at national conferences of professional organizations such as the Gerontological Society of America and the AARP; and a project to collaborate with organizations serving hard to reach audiences to raise awareness of NIA’s free health and aging information among their constituents.

NIA’s outreach activities receive a positive, albeit informal, response from older adults, caregivers, health professionals, and others who order NIA publications, visit the NIA and NIHSeniorHealth.gov websites, subscribe to NIA’s e-alerts, and interact in other ways with NIA via mail, email, and phone. However, regular formal research is necessary to make NIA’s outreach efforts evidence-based. NIA needs to determine how outreach methods should be modified, especially since preferences for sources of health information can change when new communications channels (i.e., social media) are established. More organizations are abandoning print publications for the web; however, older adults are typically the last to adopt using these new communications channels and the way they use the channels may be different than their younger counterparts. In addition, despite the success of current outreach efforts, NIA continues to reach only a fraction of its target audience. Especially given the exponential growth of the older population (sometimes called the baby boomer generation), OCPL sees a need to broaden its outreach program. Rather than depending on traditional outreach outlets and methods, NIA would like to conduct primary research to determine the best ways to get to people who need NIA health and aging information the most.

To ensure that NIA’s OCPL successfully develops and disseminates health communications on aging-related issues, NIA plans to conduct formative research with its key audiences—older people, caregivers, and health professionals. This type of research involves (1) assessing audiences’ trusted/preferred sources for information, knowledge, attitudes, behaviors, and other characteristics for the planning/development of health messages and communications strategies and (2) pretesting health messages and outreach strategies while they are in developmental form to assess audience response, including their likes and dislikes.

NIA OCPL plans to conduct formative research on its health information resources and outreach strategies to maximize their effectiveness. Such research would be conducted with specific target audiences, such as a study with older adults to determine new topic areas to explore for future NIA publications and another study with senior center administrators to determine how to support the health information needs of its members.

NIA is requesting a generic clearance for a range of research data collection procedures to support the successful health communications surrounding aging-related issues. Approval is requested for up to 18 information gathering sessions annually using methods described in Section A.2 with respondents from audiences targeted by health information materials developed by NIA. A total number of respondent burden hours will not exceed 250 annually. Individual sub-studies will be submitted for OMB review and approval once they are developed.

**A.2 Purpose and Use of the Information**

Formative research is critical for the development of effective, evidence-based communications materials and outreach strategies. Formative research will enable NIA OCPL to be most efficient in its development and dissemination of its health and aging information at the least cost to the Government.

Formative research is used to gather from a specific audience their general health/aging information needs and how they prefer to get their information. Correspondingly, formative research can be used to test whether a message or outreach strategy is effective in reaching and communicating with its audience. Testing involves the presentation of messages, materials, and outreach strategy concepts designed to convey specific information to a sample audience for which the messages/materials/strategies were intended. These respondents are asked to give their reaction through either individual or group interviews. Messages, materials, and outreach strategies are assessed for their:

* Attention--Do the messages, materials, strategies attract and/or hold the audience’s attention. For example, if they saw one of NIA’s brochures in a doctor’s office, would they pick it up and look at it? If they saw a message about NIA’s materials in their community newsletter, would they be motivated to order a publication?
* Comprehension--Are the messages or main points clearly understood? Does the take-home message about a specific health issue get across to the audience? Is the language clear and age-appropriate?
* Personal relevance and self-efficacy--Do members of the audience perceive the message or outreach strategy to be personally relevant? For example, does the audience agree that they need information about a particular health/aging topic? Does the audience use the communications channel, like Facebook, suggested for outreach? Do the respondents see the materials as able to help them or someone they know make health decisions?
* Accessibility--Will the message literally and figuratively reach the target audience? For example, is the way the information is presented helpful to the specific audience? Is the choice of communications channel appropriate? Is the strategy to raise awareness of the publication likely to be effective?
* Usability--Is the format/layout of the information user-friendly? Is the information organized in the most appropriate way for the audience?
* Behavioral Intent--Do respondents think they will use the materials to make certain health decisions in the future? Do they think that other people they know would be motivated to make specific behavior changes based on the material? What would they do with the material after reading it? In the case of outreach strategies, would the audience be motivated to access NIA’s health/aging information?

Participant response to these different categories of questions will help NIA OCPL foresee how the target audience will view materials/outreach strategies. It will provide NIA OCPL with the necessary feedback to formulate, modify messages/outreach strategies so that they are most effective. See document “Sample questions for NIA qualitative research studies” for additional example questions.

Other information gathered about participants, including gender, age, socioeconomic level, education, living situation (i.e., independent housing, nursing home), and race/ethnicity will help NIA OCPL determine if message/outreach strategies may be perceived differently among different segments of the audience. For example, one racial/ethnic group may find an outreach strategy appropriate while another group may find the same strategy ineffective.

Systematic formative research has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials. Through this research NIA will be able to:

* Understand characteristics of the target audience--its attitudes, beliefs, and behaviors--and use these in the development of effective communications tools;
* Design health/aging messages and select formats that have the greatest potential to influence the target audience’s attitudes and behavior in a favorable way;
* Determine the best outreach strategies and distribution channels to reach the target audience with appropriate health/aging materials; and
* Expend limited program resource dollars wisely and effectively.

Without clearance to conduct formative research, NIA will be unable to develop evidence-based health/aging materials and outreach strategies that are base on the needs of the target audience. We will be unable to determine whether our communications program is effective and unable to fully meet NIA’s mission.

**A.3 Use of Information Technology and Burden Reduction**

Information will be collected through one-on-one interviews, group interviews (also known as focus groups), or self-administered questionnaires, depending on the target audience being questioned and the message, materials, products or activities being addressed. Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing data maximally efficient. For example, NIA OCPL may choose to do telephone interviews when geographic diversity or the relative anonymity of a phone call is important and a face-to-face setting is not necessary to accomplish the evaluation objectives. When telephone interviews are used, computer-assisted telephone interviewing (CATI) will be employed whenever possible. NIA OCPL will, whenever possible, administer closed-ended questions (for example education, socioeconomic, and demographic questions and other multiple-choice items or Likert scales) using machine-readable answer sheets. NIA OCPL will also employ computer-administered questionnaires when feasible. Transmission of data collection instruments and responses by electronic means will be utilized as appropriate.

As computer technology has continued to improve and become more widespread, opportunities to test messages using computers and the Internet have increased. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce burden on respondents; for example, respondents can access and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for in-person or group interviews. Whenever possible, NIA will make use of Web- or computer-based data collection methods.

NIH’s Privacy Act Officer, Karen Pla, reviewed the project proposal and determined that the Privacy Act will not apply to this data collection. Please see the attached letter from Pla.

**A.4 Efforts to Identify Duplication and Use of Similar Information**

NIA has received informal feedback about its publications from people who have independently volunteered their thoughts via email, mail, phone and in-person at exhibit booths. This collection has not been systematic nor from a representative sample of NIA’s target audiences; therefore this feedback cannot be used to determine the overall success of NIA’s materials. NIA does not receive informal feedback from its target audience about NIA’s outreach strategies.

Federal agencies like Administration on Aging that may have information about the information needs of older people are focused on aging services where as NIA is focused on health and aging research; therefore information collected by the Administration on Aging cannot be applied to the needs of the NIA.

In 2009, NIA completed a small evaluation project on its *AgePage* fact sheets. As part of this project, participants were also asked their thoughts about ways to raise awareness of *AgePages*. Information was collected through small focus groups. It was from this project that NIA recognized the need for larger formal research related to all of its health and aging materials and outreach strategies. This research needs to be with a variety of its target audiences, including older people, caregivers, and health professionals. Large scale formative research about NIA’s health and aging materials and outreach strategies has not been done and there is no similar information available from other organizations.

As each new publication and outreach strategy is developed, NIA will review existing literature and data bases, including the information collected about the *AgePage* fact sheets, and consult with experts to evaluation available information on similar materials or strategies with comparable audiences. However, since each publication and outreach strategy is essentially different, new data collection instruments generally must be prepared for each formative research study.

**A.5 Impact on Small Businesses or Other Small Entities**

Community-based organizations, including senior centers, or healthcare providers may sometimes be the target audience for NIA information materials. When testing these materials requires the participation of these organizations, providers, NIA will generally work through established societies to gain access to the audiences, and to obtain feedback on NIA’s instruments and data collection plans. As a result, NIA will be able to minimize the placement of additional burden on these community-based groups and healthcare providers.

**A.6 Consequence of Collecting the Information Less Frequently**

Information will be collected only one time for each publication or outreach strategy tested. Respondents will not be re-contacted.

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

Because NIA’s activities are primarily qualitative in nature, some results may not be generalizable to the population at large, but instead represent a significant portion of the particular audience under study. However, the nature of formative research is such that generalizability is not a critical feature; the emphasis is on obtaining timely, useful information that can be fed back into the development of new health and aging materials or outreach strategies or the revisions of existing materials or strategies.

There are no other special circumstances.

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

NIH, along with other Public Health Service agencies, has been a leader in the development of methods for developing, testing, and disseminating health information. A number of NIH communications experts were consulted to review these plans for research on NIA’s communications activities. Their comments and suggestions have been incorporated into these data collection plans.

NIA submitted the required 60-day notice in the Federal Register on 09-27-2010 at 08:45:00, <http://federalregister.gov/a/2010-24277> (Vol. 75, No. 187, Page: 59723-59724 (2 pages); Document Citation: 75 FR 59723; Document Number: 2010-24277).

We received one comment from an organization requesting to be considered as a contractor for this project, which did not require a response at this time. We did not receive any other comments from the 60-day notice. We are submitting the 30-day notice in conjunction with submitting supporting statements and worksheet to OMB.

**A.9 Explanation of Any Incentive or Gift to Respondents**

NIA does not plan to provide incentives to participants for their response to research questions.

**A.10 Assurance of Confidentiality Provided to Respondents**

Information provided by respondents will be kept private to the extent permitted by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups or telephone interviews, and consent forms. Respondents will also be advised of the following: the nature of the activity, the purpose and use of the data collected, NIA sponsorship, and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions. No sensitive information, like social security numbers, health insurance information, or medical reports will be collected or used in any way in the research.

In order to protect respondents’ privacy, all presentation of data in reports will be in aggregate form, with no links to individuals preserved. Reports will be used only for research purposes and for the development of communication messages, educational materials, and outreach strategies.

Research described in this proposal are considered exempt from the “Regulations for the Protection of Human Subjects” in accordance with paragraph (b)(2) of 45 CFR Sec.46.101.

**A.11 Justification for Sensitive Questions**

Sensitive information about education and socioeconomic status collected through pre-interview questionnaires will not include any identifying information (i.e., name and contact information), data will be aggregated, and the questionnaires will be destroyed after the data is extracted.

Questions asked in an interview or group interview setting will not be of a sensitive nature. However, a question like, “What health topics are of particular interest to you, your members, or old people?” could lead to participants disclosing personal information about their health. The interviewer/moderator will take care in wording/approaching follow-up questions after sensitive information is disclosed in order to maintain the comfort of the participant(s). As noted in section A.10, participants are informed in advance about the nature of the activity and voluntary nature of participation. The interviewer/moderator makes it clear that participants do not have to respond to any questions that make them uncomfortable.

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio tapes) are not retained once the data have been extracted and aggregated; nor does the information become part of a system of records containing permanent identifiers that can be used for retrieval.

**A.12 Estimates of Hour Burden Including Annualized Hourly Costs**

The number of respondents for each information collection project will vary, depending on the nature of the material or message or outreach strategy being tested and the target audience. However, for illustrative purposes, table A. 12-1 below provides an example of a distribution of respondents and hours by type of data collection. Time to read, view, or listen to the material, message, or outreach strategy being tested is built into the “Hours Per Response” figures.

**A.12-1 Estimates of Hour Burden by Anticipated Data Collection Methods and Audience**

Note: The burden table below reflects what NIA anticipates would be accomplished over 5 years of the project. (Annual burden, therefore, is one-fifth of the total figures presented here.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of respondents/research activity | Total Number Respondents | Frequency of Response | Average Time Per Response | Total Hours (annual burden) |
| Individual In-Depth Interviews (in person or telephone) with older people | 100 | 1 | .75 | 75 (15) |
| Focus group interviews with older people | 200 | 1 | 1 | 200 (40) |
| Self-Administered Questionnaires with older people | 500 | 1 | .25 | 125 (25) |
| Individual In-Depth Interviews (in person or telephone) with non-physician health professionals, caregivers, or people who work with seniors | 100 | 1 | 1 | 100 (20) |
| Focus Group Interviews with non-physician health professionals, caregivers, or people who work with older people | 150 | 1 | 1 | 150 (30) |
| Self-Administered Questionnaires with non-physician health professionals, caregivers, or people who work with seniors | 800 | 1 | .25 | 200 (40) |
| Individual In-Depth Interviews (in person or telephone) with physicians | 50 | 1 | 1 | 50 (10) |
| Focus Groups with physicians | 50 | 1 | 1 | 50 (10) |
| Self-Administered Questionnaires with physicians | 200 | 1 | .25 | 50 (10) |
| Website surveys (presumably half with older people and half with caregivers or others who work with older people) | 1000 | 1 | .17 | 170 (34) |
|  |  |  |  |  |
| Totals | 3150 |  |  | 1170 (234) |

(Note: On an annual basis, the total number of respondents is 630; the annual number of responses is 630; and the total annual hours are 234)

Table A. 12-2 presents the cost to respondents over 5 years of the project. Annual cost, therefore, is one-fifth of the total figures shown.

**A.12-2 Cost to Respondents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondents | Number of Respondents | Frequency of Response | Hourly Wage Rate | Respondent Cost |
| Older adults | 1300 | 1 | $10.00 | $4,850.00 |
| Non-physician health professionals, caregivers, or other people who work with seniors | 1550 | 1 | $30.00 | $16,050.00 |
| Physicians | 300 | 1 | $50.00 | $7500.00 |
|  |  |  | TOTAL | $28,400.00 |

The cost to individual respondents who are older adults is approximately $3.73 based on the estimate of $10.00/hour and average respondent burden is .37 hours. The cost to non-physician health professionals, caregivers, and other individuals who work with seniors is approximately $10.35 based on the estimate of $30.00/hour and average respondent burden is .36 hours. The cost to individual respondents who are physicians is $25.00 and average respondent burden is .5 hours per respondent.

**A.13 Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There are no capital or start-up costs to the data collection efforts requested; nor are there any costs associated with operation, maintenance, or purchase of services.

**A.14 Annualized Cost to the Federal Government**

The total annual cost to the Federal Government will not exceed $100,000 per year (or $500,000 over 5 years). This estimate is based on annual performance of up to: 1 focus group study at $80,000 and one in-person, in-depth interview study at $20,000 or 2 self-administered questionnaire studies at $10,000 each ($20,000 total) or 2 Website visitor surveys at $8,000 each ($16,000 total). These figures include the cost of study design, facility rental (e.g., for focus groups), data collection, analysis, and report/publication writing.

**A.15 Explanation of Program Changes of Adjustments**

This is a new collection of information.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

The process for developing the analytical plan for this research is similar to that used in any formal research. Staff will review the material to be tested, discuss the objectives with the individuals responsible for developing the materials, determine the analytical questions to be addressed in the qualitative research, and then prepare the qualitative research procedures, instruments, and data analysis plan. The analyses conducted for each qualitative research study will be determined by the objectives of the study, the outreach messages and strategies or NIA materials being tested, and the audience for the outreach/materials. Specifics of the analyses cannot be determined until the outreach strategies or specific NIA materials to be tested are prepared. However, the analysis will be primarily qualitative. No complex analytical techniques will be used including statistical use. The following is an example of the timeline that could be used for this research:

**A.16-1 Project Time Schedule**

Start date: Approval from OMB

End date: 44 weeks after OMB approval

|  |  |
| --- | --- |
| *Week 1–week 5 (five weeks)* | Hire contractor for evaluation project, establish final moderator guide |
| *Week 3–week 7 (five weeks)* | Secure space at D.C. and second location for focus groups/in-depth interview/other qualitative research method |
| *Week 6 –week 11 (six weeks)* | Finalize focus group conversation stimulation guide/interview questions/other research instrument and informed consent |
| *Week 6 – week 15 (ten weeks)* | Recruit participants |
| *Week 16 – week 24 (nine weeks)* | Conduct focus groups/in-depth interview/other qualitative research method |
| *Week 25 – week 30 (six weeks)* | Analyze data |
| *Week 30 – week 41 (12 weeks)* | Write report |
| *Week 37* | Draft of report to NIA for first revision |
| *Week 39* | Draft back to contractor for revision |
| *Week 40 – week 43 (4 weeks)* | Prepare presentation on study findings |
| *Week 44* | Final report and presentation due to NIA |
| *Week 44* | Prepare report for online publication |

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

NIA will display OMB control number and expiration date in the upper right-hand corner of all data collection instruments.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

NIA is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act Submissions.