REQUEST FOR CLEARANCE FOR COMMUNICATIONS TESTING FOR COMPREHENSIVE COMMUNICATION CAMPAIGN FOR HITECH ACT

ICR # 201105-0990-005

Submitted by:
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A. JUSTIFICATION

A.1 Circumstances That Make the Collection of Information Necessary

This Information Collection Request (ICR) is for a new data collection entitled Comprehensive Communication Campaign for HITECH Act. The request is for three years starting from the date of OMB approval.

Background

The Office of the National Coordinator for Health Information Technology (ONC) serves as the Health and Human Services (HHS) Secretary's principal advisor on the development, application, and use of health information technology (health IT). ONC was originally created under Executive Order (EO) 13335, but has since been codified in law by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. The HITECH Act builds on EO13335 and establishes additional purposes for the ONC and duties for the National Coordinator. Chief among these new HITECH Act responsibilities are to: promote the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information; coordinate health IT policy; and update the Federal Health IT Strategic Plan to meet the objectives specified in the HITECH Act. Meeting certain objectives such as "methods to foster the public understanding of health information technology" will require additional information from the public at large to determine what education is needed and what types of communication techniques will be most effective.

Education on Health Information Privacy is mandated in the HITECH Act, Sec. 13403, to develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. ONC is collaborating with the HHS Office for Civil Rights (OCR) to oversee the education and communication activities regarding health information privacy.

ONC requests OMB approval for a generic clearance for collecting information through a variety of research methods for developing and testing communications involving health information technology and health information privacy. This information will be used to assess the need for communications on specific topics and to assist in the development and modification of communication messages. ONC intends to utilize best practices for effective health communication research set forth by other DHHS agencies such as the National Cancer Institute.[1]

ONC creates and uses a variety of media, including print (e.g., brochures, posters, fact sheets, information kits), broadcast (e.g., Public Service Announcements, video news releases), and electronic formats (e.g., Internet and listservs) to communicate with the public about health information technology and health information privacy.

[1] National Cancer Institute (NCI). Making Health Communications Work: A planner's guide, Pink Book. Pub. No. T068. Washington, DC: U.S. Department of Health and Human Services (HHS), August 2004.

To ensure that such health communication messages and materials have the highest potential to be received, understood, and accepted by those for whom they are intended, ONC will conduct research and studies relating to health information technology and health information privacy. This type of research involves 1) assessing audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, communication strategies, and public information programs; and 2) testing these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions.

Testing messages is a staple of best practices in communications research. Obtaining feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program.[2] The purpose of early testing is to improve materials and strategies while revisions are still affordable and possible. Testing can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which communication messages need to be modified should be greatly reduced.

Approval is requested for tests of communication messages using methods described in section B with respondents from target audiences. The total number of respondent burden hours will not exceed 2,619 per year. ONC will submit individual collections under this generic clearance to OMB. OMB will, in turn, provide feedback on the individual collections within ten working days, whenever possible, as is currently the case with other generic clearances. ONC will send OMB an annual report at the end of each year summarizing the number of hours used, as well as the nature and results of the activities completed under this clearance.

ONC is authorized to collect information under the Public Health Service Act Section 3011(a), as added by HITECH Section 13301. See Attachment 1.

A.2 Purpose and Use of Information Collection

ONC plans to use the data collected under this generic clearance to inform its communications campaigns. The data will help in tailoring print, broadcast, and electronic media communications for them to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The information collected will serve two major purposes. First, formative research will provide qualitative information about target audiences – their needs, decision-making processes, and misperceptions – that is critical to initial communications planning and development. Different formative research will have different foci, depending on the audience addressed and the questions needing to be answered to develop effective communications. For example, ONC must explore consumers' beliefs and perceptions about health information privacy. Qualitative information on decision-making processes will also give ONC a better understanding of the needs of its different target audiences.

[2] National Cancer Institute (NCI). Making Health Communications Work: A planner's guide, Pink Book. Pub. No. T068. Washington, DC: U.S. Department of Health and Human Services (HHS), August 2004.

ONC must also understand the general beliefs of physicians and healthcare adjuncts. Prescribers and technicians, including nurses, play a key role in the use of health information technology. ONC must determine their informational needs and the most effective communication channels and formats for reaching and educating them about the transition to an electronic records environment. This information will allow ONC to engage healthcare professionals as partners in the transition.

Second, initial testing will give ONC some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow ONC to refine messages while they are still in the developmental stage. Respondents may be asked to give their reaction to the messages in individual or group settings. Initial testing may provide information on any of the following factors.

- *Attention* - The extent to which factors such as language, placement, typography, and graphic images attract and hold the audience's attention.
- *Comprehension* – The extent to which communication messages clearly convey risks, both in terms of the needs of low-literacy audiences and with respect to plain language principles and design.
- *Personal Relevance and Self-efficacy* – Perceptions that communication messages apply to target audience members personally, that the information is considered important, and that target audience members feel they are capable of acting on the message.
- *Credibility* – Perceptions that communication messages are credible and are being issued by a trustworthy and knowledgeable source.
- *Acceptability* – Detection of negative reactions and the extent to which target audience members find communication messages to be offensive, unacceptable, or culturally insensitive.
- *Behavioral Intent* – The extent to which respondents think they will take action (for example, maintain radioactive technology according to specifications) as a result of seeing the communication messages.

Respondents' input and reactions to each of these areas provide insight into how target audiences may react and how the messages should be formulated or revised to communicate most effectively. Other information gathered on respondents' gender, age, socioeconomic level, race/ethnicity, and personal/family use of medical devices provides a basis for evaluating whether the messages may be perceived differently by various segments of the audience. For example, selected age groups may find a particular message or graphic image more compelling than other age groups.

Systematic communications testing has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials. Through communications testing ONC is able to:

- Better understand characteristics of the target audience–its attitudes, beliefs, and behaviors–and use these in the development of effective communications;

- Design messages and select formats that have increased potential to influence the target audience's attitudes and behavior in a favorable way;
- Help determine promotion and distribution channels to reach the target audience with appropriate messages; and
- Expend limited program resource dollars wisely and effectively.

A.3 Use of Improved Information Technology and Burden Reduction

The information will be collected through one-on-one telephone or in-person interviews, focus groups, web usability sessions, or self-administered surveys, depending upon the target audience being questioned, expectations about whether the information will be evaluated in an individual or group context, and the need to present visual stimuli (e.g., videos). As computer technology has continued to improve and become more widespread, opportunities to test messages on the Internet using either Web-based surveys or on-line focus groups have increased. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the 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. Wherever possible, ONC will make use of Web-based data collection methods.

Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing maximally efficient. Possible information technologies for testing include the following.

Computer-Assisted Telephone Interviewing (CATI)
Surveys conducted by telephone are well suited to the use of computer-assisted telephone interviewing technology. CATI's technological capabilities include automated dialing, scheduling unanswered calls or interrupted interviews for efficient callbacks, random selection of respondents, automated skip patterns, instantaneous out-of-range checks, insertion of information from one question to guide a subsequent question, and the automated generation of databases for subsequent analysis. When telephone interviews are used, CATI will be employed whenever possible.

Web-based Surveys
Web-based surveys, including those using experimental designs, are an especially convenient option for eliciting feedback on visual stimuli. With Web-based surveys, respondents complete an on-line survey and then submit the data electronically over the Internet. Closed-ended questions (e.g., multiple-choice items, Likert scales) will be employed whenever possible.

Videoconferencing
Videoconferencing uses video and satellite technology to allow a group of focus group participants located in multiple geographic locations to interact with one another both visually and aurally. A facilitator and a technical team located in a hub site maintain the video and audio connections among participating sites.

Internet conferencing

Internet conferencing is especially useful for discussions with specific individuals or international participants. This format functions as a sort of "chat room" in which a moderator intercepts and distributes e-mail transmissions from participants who have logged onto a specially designated Web site.

Teleconferencing
Teleconferencing uses telephone technology to facilitate an exchange among participants located in multiple geographic locations. Participants dial into a specially designated phone number or "bridge line" that is moderated by a focus group facilitator.

Web Usability Testing Laboratories
Web usability testing laboratories are outfitted with logging software used to capture keystrokes to determine what the user is typing and what menu items are selected.

A.4 Efforts to Identify Duplication

From October to December 2009, ONC conducted an extensive environmental scan that included multiple literature searches and consultations with other federal agencies working on health information technology issues. ONC identified numerous surveys from the public and private sector that ask in general about the public's knowledge of and concerns about health information privacy and security issues (including a proposed survey from ONC that is under review with OMB) but did not find prior or current research related to specific messages and sources of information about the issues addressed by this campaign. ONC did not locate any studies that are tracking public knowledge and awareness over time about privacy, security and health information exchange. ONC also conducted a content review of existing privacy and security messages and materials available to the public and providers. ONC found many gaps in information available to these two groups, reinforcing the need for the proposed educational and communication campaign.

In addition, ONC conducts regular monitoring of news media, literature and databases, and consults with outside experts to search for and evaluate available information on similar messages with comparable audiences. ONC will be working with OCR, CMS, and other government agencies that are responsible for communicating about health information technology or health information privacy to the general public.

A.5 Impact on Small Businesses or Other Small Entities

These proposed data collection activities will focus primarily on subjects in their roles as individuals during their own time. In some instances we might want to question hospital or other healthcare facilities staff. In most cases, we believe that such facilities are very unlikely to include small businesses, and we will strive to avoid including small businesses unless they are a targeted audience. If we believe that employees of small businesses should be examined, we will ensure understanding that the information collection is completely voluntary. We anticipate the burden on small businesses or other small entities as no more than one hour per respondent.

A.6 Consequences of Collecting the Information Less Frequently

ONC plans to use a variety of media, messages, and materials to inform and educate the public. Sound research and evaluation are needed as integral parts of communication design rather than as afterthoughts. Unless the public understands communications about health information technology and health information privacy sufficiently well to make appropriate choices, ONC will not be serving the public as mandated.

Without testing, ONC could be expending considerable funds on communications that will not achieve the intended purpose of improving public health. ONC intends to test as frequently as is appropriate to ensure that communications are appropriately designed. Testing on an ad hoc basis will be needed to assess initial and continuing relevance of messages given dynamic social and environmental factors and the changing education and information needs of the public.

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

Because ONC's communications testing activities will be primarily qualitative in nature, the results are not generalizable to the population at large or the particular target audience under study. However, the nature of communications testing 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 messages or materials or the revision of existing ones. There are no other special circumstances.

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

A. NOTICE AND SUMMARY OF COMMENTS, IF ANY, TO BE PROVIDED WHEN AVAILABLE. The notice in the *Federal Register* (Vol. 75, No. 073, April, 16, 2010, p. 19974) soliciting comments is shown in Attachment 2a. A comment from the Consumer Engagement Workgroup of the Missouri Office of Health Information Technology (MO-HITECH is shown in Attachment 2b.

B. Since 2009, the Agency has consulted with the following persons regarding this information collection.

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A.9 Explanation of any Payment or Gift to Respondents

It is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in a personal interview activity. Instances for offering a small incentive will be determined on a case-by-case basis (depending on the particular information collection design).

As standard practice in commercial market research, and as has been approved by OMB in the past, focus group participants may be offered an incentive at a regionally appropriate market rate (but no more than $40 for a cognitive interview or $75 for a 90-minute focus group). ONC will provide a rationale in the justification memo for any studies that propose to offer rates beyond these amounts. For example, incentives for Web-based or telephone focus groups may be offered at a lower rate. Incentives for difficult-to-recruit populations, including some health professional audiences, may be offered at a higher rate, with the upper bound at $300 for certain medical specialists.

Circumstances, however, do not always require that remuneration be given; many audiences including the public, patients, and some health professionals may participate at their own expense because of their interest or involvement in the topic, or as a professional courtesy.

A.10 Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private and anonymous, except as otherwise required 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 also will be advised of the following: the nature of the activity; the purpose and use of the data collected; ONC sponsorship (when appropriate[3]); 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.

Only personnel from a contractor conducting the information collection will have access to individual-level survey, interview, or focus group data. All project staff from a contractor conducting the information collection must take required measures to ensure the privacy and anonymity of data. All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, 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.

A.11 Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that ONC is trying to reach. This may require asking a question about race/ethnicity, income, education and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that ONC speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as private and anonymous. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

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. The information is never a part of a system of records containing permanent identifiers that can be used for retrieval.

A.12 Estimates of Annualized Burden Hours and Costs

Table 1 is based on the maximum number of data collections expected on an annual basis. It is highly unlikely that respondents will be contacted more than once per year due to the evolving nature of health information technology and the need to address different respondent groups. Proposed data collection methodologies are described in more detail in Section B.

[3] In some cases, ONC sponsorship will not be made known to respondents prior to data collection out of concern for the potential introduction of bias to study results. In such cases, ONC sponsorship will be made known after the data are collected.

Table 1. Estimated Annual Reporting Burden, by Anticipated Data Collection Methods

	Number of Respondents	Frequency of Response	Hours Per Response	Total Hours
General Public Focus Group Interviews	144	1	1.50	216
Screening for General Public Focus Group Interviews	2,160	1	10/60	360
Web usability testing sessions	144	1	1.50	216
Screening for Web usability testing	2,160	1	10/60	360
Self-Administered Surveys	2,000	1	15/60	500
Screening for Self-Administered Surveys	8,000		10/60	1,333
Omnibus Surveys	2,000	1	10/60	333
Cognitive testing of survey instruments	25	1	2	50
TOTAL (General Public)	16,633			3,368
Health Professional Focus Group Interviews	144	1	1.50	216
Screening for Professional Focus Group Interviews	2,160	1	10/60	360
Web usability testing sessions	144	1	1.50	216
Screening for Web usability testing	2,160	1	10/60	360
Self-Administered Surveys	2,000	1	15/60	500
Screening for Self-Administered Surveys	8,000		10/60	1,333
Omnibus Surveys	2,000	1	10/60	333
Health Professional Individual In-Depth Interviews	100	1	45/60	75
Screening for Health Professional Individual In-Depth Interviews	1,000	1	10/60	167
TOTAL (Physician and Other Health Professional)	17,733			3,560
TOTAL (Overall)	34,366			6,928

The average salary for the general public group is $30.02.[4] Other labor groups include primary care physicians, nurses/nurse practitioners, and practice administrators (medical services managers), whose average salary, respectively, is estimated as $119.15, $31.99, and $43.74.[5]
The estimated annualized annual costs are outlined in Table 2.

Table 2. Estimated Annual Costs			
Audience	Wages	Total Hours	Total Costs

[4] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010.
[5] U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010.

General Public Focus Group Interviews	$30.02	216	$ 6,484.32
Screening for General Public Focus Group Interviews	$30.02	360	$10,807.20
Web usability testing sessions	$30.02	216	$ 6,484.32
Screening for Web usability testing	$30.02	360	$10,807.20
Self-Administered Surveys	$30.02	500	$15,010.00
Screening for Self-Administered Surveys	$30.02	1,333	$40,016.66
Omnibus Surveys	$30.02	333	$ 9,996.66
Cognitive testing	$30.02	50	$1,501.00
TOTAL (General Public)		3,343	$101,107.36
Health Professional Focus Group Interviews			
- Physicians	$119.15	108	$12,868.20
- Nurses/nurse practitioners	$31.99	54	$ 1,727.46
- Practice administrators	$43.74	54	$ 2,361.96
Screening for Professional Focus Group Interviews			
- Physicians	$119.15	180	$21,447.00
- Nurses/nurse practitioners	$31.99	90	$ 2,879.10
- Practice administrators	$43.74	90	$ 3,936.60
Web usability testing sessions	$119.15	216	$25,736.40
Screening for Web usability testing	$119.15	360	$42,894.00
Self-Administered Surveys			
- Physicians	$119.15	250	$29,787.50
- Nurses/nurse practitioners	$31.99	125	$ 3,998.75
- Practice administrators	$43.74	125	$ 5,467.50
Screening for Self-Administered Surveys			
- Physicians	$119.15	666	$79,353.90
- Nurses/nurse practitioners	$31.99	334	$10,684.66
- Practice administrators	$43.74	333	$14,565.42
Omnibus Surveys	$119.15	333	$39,676.95
Health Professional Individual In-Depth Interviews	$119.15	75	$ 8,936.25
Screening for Health Professional Individual In-Depth Interviews	$119.15	167	$19,898.05
TOTAL (Physician and Other Health Professional)		3,585	$340,815.36
TOTAL (Overall)		6,928	$441,922.72

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

No capital or start-up costs will be incurred as a result of these information collection activities.

A.14 Estimates of Annualized Costs to the Federal Government

Costs will include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting on findings. Because this request for generic clearance includes various procedures for the collection of information, contractor expenses may vary from an estimated $20,000 for a focus group study to an estimated $100,000 for an in-depth interview study. The maximum estimated annualized expense for contractor expenses in this data collection is $600,000.

In addition, government staff costs may be incurred for monitoring by the government Project Officer, projected to be about 25% of an FTE's time per year (522 hours). Given an ONC personnel cost of $57.13 per hour, $29,708 would be spent annually on government staff salaries.

The total estimated annual cost to the government for this collection of information is $629,708, This is equal to the total of contractor expenses ($600,000) plus ONC government staff salary cost ($29,708).

A.15 Explanation for Program Changes or 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 communications testing is similar to that used in any formal evaluation. The staff will review the material to be tested, discuss the objectives with the individuals responsible for developing the materials, determine the analytic questions to be addressed, and then prepare the procedures, instruments, and data analysis plan. The analyses conducted for each project will be determined by the communication objectives, the messages being tested, and the audience for the messages. Specifics of the analyses cannot be determined until the messages to be tested are prepared.

Techniques include primarily qualitative analyses (for example, content analysis for in-depth interviews), although some results, including those from central location intercept interviews or Web-based surveys, are summarized quantitatively using descriptive statistics. In cases where quantitative data is collected, descriptive statistics—including percentages, cross tabulations, and averages—will be calculated and presented, along with demographic descriptions of study respondents. Information collected from study participants will be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race/ethnicity, etc.). Statistical analyses may be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; non-parametric procedures will be used otherwise. All of the analyses will be done in the context of

understanding the limitations of the data with respect to their not representing population parameters.

While the primary purpose of this data collection is to provide information to the developers of the messages for the purpose of improving them, ONC makes results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, ONC may present the findings of its work at professional association meetings, including those of the American Public Health Association. Some results may be published in professional journals such as the *Journal of Public Policy and Marketing*. In any findings presented at professional association meetings or in professional journals, ONC will state the limitations of the data by recognizing the qualitative and nonrepresentative nature of the results.

The specific messages to be tested and the timing of these messages are not known at this time. While the period varies somewhat depending on the complexity of the testing and number of respondents required, the typical communications testing project will require approximately 12 weeks once OMB clearance is obtained. A schedule for a typical project is shown below:

Project Time Schedule

Activity	Time Schedule
Finalize materials	1 week after OMB approval
Finalize design	3 weeks after OMB approval
Collection of data	5 weeks after OMB approval
Analysis of data	10 weeks after OMB approval
Report on results	12 weeks after OMB approval

A.17 Reasons Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification for paperwork reduction act submissions are requested.