**Memorandum**

**To: Margo Schwab and Josh Brammer, Office of Management and Budget**

**Through: Sherette Funn-Coleman, ONC Information Clearance Officer**

**From: Peter Garrett and Christy Choi, ONC**

**Date: July 7, 2011**

**Re: Under Approved Generic OMB Control No: 0990-0376;**

 **ICR Reference No: 201106-0990-003**

**Request Approval to Conduct Focus Groups to Test Messages and Materials**

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The Office of the National Coordinator for Health Information Technology (ONC) is requesting approval for communications testing under Approved Generic OMB Control No. 0990-0376.

The following content and information is provided for your review:

1. Title of Project: Communications Testing for Comprehensive Communication Campaign for HITECH Act

The research includes in-person focus groups among consumers and health professionals to test messages and materials related to health IT and the privacy and security of personal health information.

1. Control Number: 0990-0376, expiration date 07/31/2014.
2. Public affected by this Project:
* **Health professionals**: We are proposing to test messages and materials in support of public communication for the HITECH Act among primary care physicians, including family/general practitioners, internists, and pediatricians. We will also test messages and materials among nurse practitioners and physician assistants.
* **Consumers**: Because Education on Health Information Privacy in a variety of languages is mandated in the HITECH Act, Sec. 13403, we are proposing to test messages and materials among general adult consumers who speak the following languages, which are among the most widely spoken languages in the U.S. apart from English:
	+ Spanish
	+ Chinese
	+ Tagalog
	+ Vietnamese
	+ Russian
	+ Korean

In addition to general adult consumers who speak the languages listed above, we will also test messages and materials in English among two segments of adult consumers, those with diabetes and those who are caregivers of or primary health decision makers for a family member, loved one or friend. We are interested in the views of these segments of consumers because they are higher users of the health care system compared to the general adult population.

A total of 32 focus groups will be conducted July-August 2011, in four markets: Washington, D.C.; New York, NY; Chicago, IL; and Los Angeles, CA. We will recruit **9** participants for each consumer focus group and **8** participants for each professional group, for atotal of **272** participants (144 consumers and 128 health professionals).

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| **May-June Focus Groups** | **Number of Focus Groups Per Location** |
| Audience | Washington, DC | Chicago, IL | New York, NY | Los Angeles, CA | **Total** |
| **Health Professionals** |
| Primary care physicians | 3 | 3 | 3 | 3 | **12** |
| Nurse practitioners/ physician assistants | 1 | 1 | 1 | 1 | **4** |
| **Total Number of Professional Focus Groups Per Market** | **4** | **4** | **4** | **4** | **16** |
| **Total Number of Professionals Per Market** | **32** | **32** | **32** | **32** | **128** |
| **Consumers** |
| Spanish speakers | 0 | 2 | 0 | 0 | **2** |
| Chinese speakers | 0 | 0 | 2 | 0 | **2** |
| Tagalog speakers | 0 | 0 | 2 | 0 | **2** |
| Vietnamese speakers | 2 | 0 | 0 | 0 | **2** |
| Russian speakers | 0 | 0 | 0 | 2 | **2** |
| Korean speakers | 0 | 0 | 0 | 2 | **2** |
| Consumers with diabetes | 1 | 1 | 0 | 0 | **2** |
| Caregivers or primary health care decision makers | 1 | 1 | 0 | 0 | **2** |
| **Total Number of Consumer Focus Groups Per Market** | **4** | **4** | **4** | **4** | **16** |
| **Total Number of Consumers Per Market** | **36** | **36** | **36** | **36** | **144** |

1. Time needed per Response:

**Focus Groups:** Based on the assumption that the average length of screening for the focus group sessions will be 10 minutes per participant, the burden hours associated with 4,080 screening participants is 680 hours (10 minutes x 4,080 = 40,800 minutes = 680 hours).

Based on the assumption that the average length of the focus group discussions will be 90 minutes per participant, the burden hours associated with 272 focus group participants is 408 hours (90 minutes x 272 = 24,480 minutes = 408 hours).

**Total burden hours associated with the data collection is 1,088 hours.**

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| ***Estimated Annual Reporting Burden, by Anticipated Data Collection Methods***   |
|  | Number of Respondents | Frequency of Response | Hours Per Response | Total Hours |
| Consumer Focus Group Interviews | 144 | 1 | 1.50 | 216 |
| Screening for Consumer Focus Group Interviews | 2,160 | 1 | 10/60 | 360 |
| Health Professional Focus Group Interviews | 128 | 1 | 1.50 | 192 |
| Screening for Professional Focus Group Interviews | 1,920 | 1 | 10/60 | 320 |
| **Total** | **4,352** | **--** | **--** | **1,088** |

1. 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. According to the HITECH act, the education effort must be conducted in a variety of languages and present information in a clear and understandable manner. Therefore, testing of messages and materials in a variety of languages is essential to the effort, to ensure consumers understand topics related to protected health information.

ONC is collaborating with the HHS Office for Civil Rights (OCR) to oversee the education and communication activities regarding health information privacy.

1. Methodology for Focus Groups

Focus Group Objectives:

* Better understand characteristics of the target audiences, including attitudes, beliefs, and behaviors regarding health IT and the privacy and security of personal health information;
* Use these insights in the continual development of effective communications;
* Test messages and materials that have increased potential to influence target audiences’ 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.

Methodology, Design and Data Analysis:

*Screening*: ONC and OCR will conduct focus groups among 272 adult participants in four locations. In selecting locations and recruiting participants, we will ensure geographic diversity to represent a range of American communities, as well as socioeconomic and attitudinal diversity among consumers. The focus group sessions will be conducted in-person. Each participant will be asked to attend a single session. Participants will be recruited in each of the four cities in which we will conduct research by local recruiting resources in those cities. Participant positions will be filled through use of opt-in databases of local residents that they maintain. Interested participants will be screened by professional recruiters to assure that they meet the specific target audience requirements required by the research.

*Incentives for participants:* Focus group participants are typically provided with an incentive – usually a cash or check payment at the close of their research session. The standard rate provided by commercial facilities begins at $75 for general consumers, plus, at times, additional reimbursement for parking and/or travel expenses. We anticipate the total incentive/travel reimbursement offered to each consumer participant to be $75; to each physician participant to be $250; and to each nurse practitioner and physician assistant participant to be $175.

*Confidentiality:* **Participants are assured by the research facility, and always by the moderator at the beginning of each group, that their names and responses are kept confidential,** and will not be disclosed to anyone but the individuals conducting research in this investigation, except as otherwise required by law. **They are also assured that no one will try to sell them anything following this research.**

Outcome:

The focus group data will be reviewed for recurring themes. Preliminary and final summary reports will be provided for all research components. A final summary report of the surveys will be both descriptive and quantitative in nature, but is not intended to be generalizeable to populations beyond participants. Findings will be used to modify messages and materials if necessary to respond to the needs of the ONC and OCR constituencies. Differences across group location and audience will be noted when appropriate, but given the qualitative nature of this research, findings will be considered descriptive and directional but not definitive.

1. Federal Costs: $300,000 for the focus groups
2. Requested Approval Date: July 22, 2011
3. Formative Research Instruments:
	1. Screening questionnaires for consumer focus groups (attachments A1, A2, A3)
	2. Screening questionnaire for health professional focus groups (attachment B1, B2)
	3. Moderator guide for consumer focus groups (attachment C)
	4. Moderator guide for health professional focus groups (attachment D1, D2, D3, D4)