

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; Revised July 22, 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

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.

2. Control Number: 0990-0376, expiration date 07/31/2014.
3. 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:
 - o Spanish
 - o Chinese
 - o Tagalog
 - o Vietnamese
 - o Russian
 - o 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 a total of **272** participants (144 consumers and 128 health professionals).

August 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	0	2	2
Tagalog speakers	0	0	2	0	2
Vietnamese speakers	2	0	0	0	2
Russian speakers	0	0	2	0	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

4. 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.

<i>Estimated Annual Reporting Burden, by Anticipated Data Collection Methods</i>				
	<u>Number of Respondents</u>	<u>Frequency of Response</u>	<u>Hours Per Response</u>	<u>Total Hours</u>
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

5. 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.

6. 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:

Recruitment and 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.

Recruitment strategy for each audience segment is outlined as follows:

Primary Care Physicians (PCPs): These participants will be recruited from facilities' opt-in recruiting databases, which contain numerous physicians per location and offer the most expedient and cost effective means of recruiting. If necessary recruitment may be expanded through referrals from database participants, who provide to the recruiter the name of a physician who might be interested. The recruiting process begins with emailing or faxing a random selection of doctors a sheet of relevant information, including dates of research, times of research, recruiter to contact, and some general information regarding the topic of the research. These emails/faxes are followed up with a phone call by recruiters to ensure that the fax was received and to answer any potential questions. If the doctor is available, they are screened on

the call or, if needed, the recruiters schedule a time to call them back to be screened for eligibility in the study.

Nurse Practitioners (NPs): These participants will be recruited at random from both facilities' opt-in recruiting databases and through referrals from database participants, who provide to the recruiter the name of an NP who might be interested. The recruiting process begins by emailing or faxing the NP a sheet of relevant information including dates of research, times of research, recruiter to contact, and some general information regarding the topic of the research. These emails/faxes are followed up with a phone call by recruiters to ensure that the fax was received and to answer any potential questions. If the NP is available, they are screened on the call or, if needed, the recruiters schedule a time to call them back to be screened for eligibility in the study.

Physician Assistants (PAs): While there may be a few PAs in facilities' opt-in databases, this audience will be recruited from referrals for a more targeted and cost-effective approach. To obtain referrals, facilities will fax/call physicians at random from their opt-in recruiting databases, asking them if they have a PA in their practice or if they know of any who may be interested in the study. Facilities will also use local online website/directories to obtain phone numbers to call. During the call, recruiters will ask to fax the PAs further information, including dates of research, times of research, recruiter to contact, and some general information regarding the topic of the research. These faxes are followed up the next day with a phone call by recruiters to ensure that the fax was received and to answer any potential questions. If the PA is available, they are screened on the call or if needed, the recruiters schedule a time to call them back to be screened for eligibility in the study.

Diabetes Patients: These participants will be recruited at random from facilities' opt-in recruiting databases, which offer the most expedient and cost effective means of recruiting. In some cases, potential participants in the database will have previously indicated they have diabetes, and they will be contacted directly. In other cases, facilities will send an email to their entire database with general information about the study and a link to the screening questionnaire (Attachment A3). Seemingly qualified participants will then be called back and run through the full screening process to confirm eligibility.

Caregivers: Facilities will send a series of emails to their opt-in databases targeting potential participants in the age range of 40s & 50s. The emails will include general information about the study and a link to the screening questionnaire (Attachment A2). Seemingly qualified participants will then be called back and run through the full screening process to confirm eligibility.

Spanish Language Consumers: These participants will be recruited at random using opt-in recruiting databases provided by our foreign language recruiting resource and by the focus group facility in which the groups will be held, utilizing the most expedient and cost effective means of recruiting. Recruiting will be conducted by telephone in Spanish by Spanish-language recruiters. As potential participants are identified, they will be run through the full screening process and invited to the focus groups by the Spanish-language recruiters.

Chinese Language Consumers: The focus group facility being used for these groups will enlist

the assistance of a consulting Asian recruiter, who will assign a Chinese language (Mandarin and Cantonese) recruiter to recruit participants in language. The Asian consulting recruiter will make use of an opt-in database as well as community organizations to identify a random selection of potential participants, who will then be screened in language by the Chinese-language recruiter.

Korean Language Consumers: The focus group facility being used for these groups will enlist the assistance of a consulting Asian recruiter, who will assign a Korean language recruiter to recruit participants in language, utilizing the most expedient and cost effective means of recruiting. The Asian consulting recruiter will make use of an opt-in database as well as community organizations to identify a random selection of potential participants, who will then be screened in language by the Korean-language recruiter.

Vietnamese Language Consumers: The Vietnamese language recruiting resource being used for these groups will contact community organizations and community referral sources they have worked with previously to identify a random selection of potential participants, who will then be screened in language by the Vietnamese-language recruiter(s) and invited to the groups.

Russian Language Consumers: These participants will be recruited at random using opt-in recruiting databases provided by our foreign language recruiting resource and by the focus group facility in which the groups will be held, as well as from community resources. This approach represents the most expedient and cost effective means of recruiting. Recruiting will be conducted by telephone in Russian by Russian-language recruiters. As potential participants are identified, they will be run through the full screening process and invited to the focus groups by these Russian language recruiters.

Tagalog Language Consumers: The Tagalog language recruiting resource being used for these groups will contact community organizations and community referral sources they have worked with previously to identify a random selection of potential participants, who will then be screened in language by the Tagalog language recruiter(s) and invited to the groups. This approach represents the most expedient and cost effective means of recruiting.

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 is \$75 for general consumers. 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 generalizable 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.

6. Federal Costs: \$300,000 for the focus groups

7. Requested Approval Date: July 22, 2011

8. Formative Research Instruments:

Note: The research instruments are in English, as our foreign-language moderators are fluent in English and their focus language. They will translate the guides as they lead the focus group sessions.

- a. Screening questionnaires for consumer focus groups (attachments A1, A2, A3)
- b. Screening questionnaire for health professional focus groups (attachment B1, B2)
- c. Moderator guide for consumer focus groups (attachment C)
- d. Moderator guide for health professional focus groups (attachment D1, D2, D3, D4)

9. Stimuli (Materials for Tested) – included in PDF file as supplemental document

- 1) OCR Factsheet Template – blank graphic template that will be used for all factsheet content
- 2) OCR Factsheet: “Your Health Information Privacy Rights”
 - a) English - Caregivers
 - b) Chinese (Simplified)
 - c) Chinese (Traditional)
 - d) Korean
 - e) Russian
 - f) Spanish
 - g) Tagalog
 - h) Vietnamese
- 3) OCR Factsheet: “Sharing Information with Family and Friends”
 - a) English – Caregivers
 - b) Chinese (Simplified)
 - c) Chinese (Traditional)
 - d) Korean
 - e) Russian
 - f) Spanish

- g) Tagalog
 - h) Vietnamese
- 4) OCR Factsheet: “A Patient’s Guide to the HIPAA Privacy Rule”
 - a) English
 - b) Chinese (Simplified)
 - c) Chinese (Traditional)
 - d) Korean
 - e) Russian
 - f) Spanish
 - g) Tagalog
 - h) Vietnamese
 - 5) OCR Tagline: “Know Your Rights.”
 - a) English – Caregivers & Diabetics
 - b) Chinese (Simplified)
 - c) Chinese (Traditional)
 - d) Korean
 - e) Russian
 - f) Spanish
 - g) Tagalog
 - h) Vietnamese
 - 6) OCR Storyboard: “Know Your Rights”
 - a) English – Caregivers & Diabetics
 - 7) Campaign Concept: “Putting the I in Health IT”
 - a) English – Diabetics
 - 8) ONC MUVer Ad: Dr. Brull
 - a) Converted & Not Planning Health Professionals
 - 9) One-page containing message about MUVER program
 - a) Converted Health Professionals
 - 10) ONC Factsheet: “Meaningful User/Certification Resources from ONC and CMS”
 - a) Converted Health Professionals
 - 11) ONC Factsheet: “Direct Project Pilot Programs”
 - a) Converted Health Professionals
 - 12) Tri-fold Brochure: “What Patients Need to Know about EHRs”
 - a) Converted Health Professionals
 - 13) One page containing the three messages about RECs, Workforce and HIE
 - a) Planning Health Professionals

- 14) ONC MUVer Ad: Dr. Garber
 - a) Planning Health Professionals
- 15) ONC Factsheet: “Facts about RECs”
 - a) Planning Health Professionals
- 16) ONC Factsheet: “How to Talk to Your Patients about EHRs”
 - a) Planning Health Professionals
- 17) One page containing the three messages about benefits and penalties
 - a) Not Planning Health Professional
- 18) ONC Factsheet: “Advancing the Future of Health Care with the Electronic Health Records”
 - a) Not Planning Health Professional
- 19) ONC Factsheet: “Using EHRs to Improve Health Care in Your Practice and Community”
 - a) Not Planning Health Professional
- 20) Document on health IT adoption and/or privacy and security of EHRs
 - a) Health Professionals Nurses and PAs