



Office of the National
Coordinator for Health
Information Technology
U.S. Department of Health and
Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

May 1, 2012

Joshua Brammer
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Re: Under Approved Generic OMB Control No: 0990-0376, expiration date 07/31/2014; ICR
Reference No: 201106-0990-003
Request Approval to Administer Focus Group Sessions Across Patient Population

Dear Mr. Brammer:

The Office of the National Coordinator for Health Information Technology (ONC), Office of the Chief Privacy Officer (OCPO), is requesting approval for administering a series of focus group sessions under Approved Generic OMB Control No. 0990-0376. Specifically, OCPO requests approval to conduct focus group sessions with patients regarding mobile health privacy and security issues using the attached moderator's guide and questionnaire.

The specific focus group session and data collection methods proposed for coverage by Approved Generic OMB Control No: 0990-0376 are described below.

Background

Executive Order 13335 of April 27, 2004 established the position of National Health Information Technology Coordinator within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS). More recently, on February 17, 2009, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) established within HHS an Office of the National Coordinator for Health Information Technology (ONC). Additionally, Section 3001(e) of the HITECH Act authorized the appointment of a Chief Privacy Officer (CPO) of the Office of the National Coordinator to advise ONC on privacy, security, and data stewardship of electronic health information. The CPO is also required to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

ONC serves as the Secretary's principal advisor on the development, application, and use of

health information technology (health IT). The HITECH Act requires ONC to promote necessary privacy and security protections for health information as the electronic use and exchange of health information is encouraged and developed; coordinate health IT policy; and ensure the inclusion of meaningful public input in the development of a nationwide health information technology infrastructure.

mHealth Focus Group Summary

The purpose of the mHealth focus group information collection is to identify and explore the attitudes and preferences of patients, across different age groups, with respect to mobile health (mHealth) privacy and security concerns. Privacy and security related concerns in mHealth have yet to be well articulated or formulated, however the adoption of mHealth technology is increasing rapidly. The use of mobile devices to deliver health information has been identified as one means by which health care access may be increased for the general population, and mHealth technology could also prove to be a “leapfrog” technology, bringing improved health care to medically underserved populations. Because of the growing adoption of mHealth technology, and the significant role such technology is poised to play in health care delivery, ONC is seeking to understand critical privacy and security issues related to mHealth by conducting a series of 24 interrelated focus groups in five regions of the country with various subsets of the population.

Public Affected by this Project

Adult Health Care Consumers: We are proposing to facilitate focus group sessions among general adult health care consumers in five geographically diverse regions of the country, including both urban and rural areas. Focus group participants will include a broad audience of mobile phone users, with a special emphasis on the medically underserved in both urban and rural settings, low income individuals, and minority groups. Additionally, focus group participants will include individuals who represent the following key characteristics and geographic and demographic factors:

- Higher education and lower education, with education as a proxy for health literacy
- English-speaking and Spanish-speaking
- Different age categories

Purpose of mHealth Focus Group Sessions

The purpose of the mHealth focus group sessions is to identify and explore consumer attitudes, concerns, preferences, and decision-making in regard to privacy and security when using mobile devices to communicate health information.

Focus Group Session Methodology

ONC proposes to conduct a total of 24 focus groups in five diverse geographic areas, with each focus group being composed of 10 - 12 participants, females and males, yielding a maximum of approximately 288 participants nationwide. The number of focus groups held in a rural or urban setting is evenly balanced at 12 each, and the data collection plan calls for six Spanish-speaking

focus groups and 18 English-speaking focus groups. In each of the geographic areas, Community Based Organizations (CBOs) will assist in recruiting participants for the focus groups according to IRB stipulated requirements.

All participants will have consented prior to their participation in a focus group, and it will be made clear that participation is voluntary. The duration of each focus group will be two hours from start to finish, which includes the pre-focus group questionnaire, the moderated portion of each focus group, and the post-session paperwork. After consent, participants will complete a demographic and technology use questionnaire before participating in the focus group. Each focus group will be conducted by an experienced moderator, who will ask the various questions and manage the overall session. The focus groups will be audio taped and each session will be transcribed by a transcription service. In addition to the moderator, there will be an observer in the room who will take notes on the meeting. It is anticipated that the moderated portion of each focus group session will last approximately 90 minutes.

Explanation of Payments/Gifts to Respondents

Each participant will be offered an incentive of \$50 for participating in the focus group session.

Estimates of Burden Hours

Estimated Annualized Burden Hours

Type of Information Collection	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden hours
Participant Screening & Recruitment/Focus Groups	288	1	2 1/6	624
Total	288	1	2 1/6	624

Estimated Annualized Burden Costs

Type of Information Collection	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
Recruitment & Participation in Focus Groups	624	\$20.99	\$13,098
Total	624	\$20.99	\$13,098

*Based upon the average wages for All Workers, Occupational earnings tables: United States, December 2008 – January 2010 (average reference date July 2009); Table 1, U.S. Department of Labor, Bureau of Labor Statistics, available at <http://www.bls.gov/ncs/ncswage2009.htm>, last visited April 25, 2011.

Cost to the Government

The total cost for the focus group sessions is estimated to be \$13,098.

Requested Approval Date: April 23, 2012