



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

March 16, 2012

Margo Schwab, Ph.D.
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 Dr. Schwab:

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 and evaluate responses after delivering the proposed information entitled, "General Education Information," followed by a facilitated question and answer session.

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

Background

ONC serves as the principal advisor to the Secretary of the U.S. Department of Health and Human Services (HHS) 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 (HITECH) Act. 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.

Additionally, Section 3001(e) of the Public Health Service Act authorizes the National Coordinator to, “appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and 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.”

eConsent Pilot Summary

ONC understands the challenges related to health information sharing and the issues of patient consent. Health Information Exchanges (HIE’s), along with the Regional Health Information Exchanges (RHIO’s), and the various participating health service providers, must be able to provide clear, comprehensive, succinct, meaningful and easily understood education on the issues of patient choice. From a national perspective, health reform in this country is heavily dependent upon the patient population recognizing, appreciating, and being willing to participate in the sharing of their health information. This is one of the key goals of the Federal Health Information Technology Strategic Plan and it is reinforced by recent Health Information Technology Policy Committee (HITPC) publications.

The scope of this project includes the responsibility of identifying the key informational elements required to educate patients, the challenge of developing key educational material and resources so providers can educate patients, the requirement to develop effective, efficient, and innovative means of delivering and communicating this information, and the need to assess how well a patient both understood and responded to the presented material.

This project has a three-phased approach to gather inputs from patients. Patient input will be solicited for Phase 1 via surveys. Phase 2 inputs will collect information from patients during focus groups. Selected patients will have an opportunity to evaluate the process and education content during Phase 3, immediately following the patient’s interaction with the eConsent Trial.

Public Affected by this Project

Adult Health Care Consumers: We are proposing to facilitate focus group sessions among general adult health care consumers at the following locations: Women’s Christian Association (WAC) Hospital in Jamestown, NY, and the Veterans’ Affairs Hospital in Buffalo, NY. The focus group sessions will begin with a presentation delivering general educational material on informed consent, HIE’s and options regarding consent. This material will use the clearest language possible to elicit feedback from participants with low-health literacy, based off of demographic indicators. Additionally, our focus group population will be representative of the ethnic and socio-demographic characteristics of the region’s population.

Purpose of Focus Group Sessions

The purpose of the focus group sessions is to elicit information from adult health care consumers about information they deem necessary prior to giving informed consent to share their personal

medical information across a network of providers. The key is to understand the information patients indicate they need to make a meaningful, informed decision regarding patient choice.

Focus Group Session Methodology

The methodological design of this proposed effort is consistent with the design of typical focus group session elicitation methods. The analysis will be both quantitative and qualitative.

Focus groups will be administered to explore preliminary key element findings identified through the survey responses. Fifty focus group participants will be selected randomly from active patients from health care providers within the HEALTHeLINK (one of the partners on the project) network. A \$50 incentive will be provided to ensure adequate and representative patient participation.

We will aim to reach a representative segment of the patient population via our scheduling process. However, we do not plan to collect nor store personally identifying information on the participants.

For two days, 25 participants will be scheduled and organized into small, facilitated groups of 6-8 participants each. Focus group sessions will be held in easily accessible locations which offer free (or validated) parking and access to public transportation. Sessions will be formally facilitated by members of the APP Design team to allow for input by each participant. A facilitator guide will be used to ensure consistent messaging during each session. Each session will be scheduled for no more than 90 minutes including debrief. The formal elicitation will last 60 minutes.

HEALTHeLINK will coordinate patient focus groups to validate and explore findings from the survey responses. After delivering general educational material, we will facilitate discussion with the focus groups to qualitatively scope key factors identified from the survey results. We will use “Paired Comparisons” techniques to assist patients in ranking the factors when no consensus can be achieved. This technique enables the group to vote on a set of two factors to determine which is more important in a focused manner. This process is repeated until all factors have been compared, resulting in a prioritized set of factors. This approach is effective in developing a consensus prioritization when confronted with a number of complex alternatives. Through prioritization of key consent educational factors most important to the patients, we will be able to better structure presentation of consent education to meet patient priorities.

Explanation of Payments/Gifts to Respondents

Our Team intends to offer an incentive of \$50 to each respondent for participating in the focus group session.

Estimates of Burden Hours

The table below shows the estimated burden for the proposed focus group sessions based on 50 participants to be involved in 90-minute sessions.

| Type of Respondent | Number of Participants | Number of Responses per Respondent | Average time of Focus Group Session (in hours) | Total Burden Hours |
|-------------------------|------------------------|------------------------------------|--|--------------------|
| Focus Group Participant | 50 | 1 | 1.5 | 75 |

The table below shows the estimated costs for the proposed focus group sessions based on the estimated burden of 75 hours. The average salary for the general public group is \$30.02.¹

| Type of Respondent | Total Burden Hours | Average Hourly Wage Rate (in dollars) | Total Respondent Cost |
|-------------------------|--------------------|---------------------------------------|-----------------------|
| Focus Group Participant | 75 | \$30.02 | \$2,251.50 |

Cost to the Government

The total cost for the focus group sessions is estimated to be \$5,534. This cost estimate includes travel expenses for the facilitators (at advertised GSA rates), and the compensation for the focus group participants.

Requested Approval Date: 06 Apr 2012

Attachment 1: General Educational Material to be presented to focus group participants

¹ U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm, June 2010.