MEMORANDUM

To: Brenda Aguilar, Office of Management and Budget

Through: Moneke D. Stevens, Information Collections Officer (HHS)

From: Sarah Plante, ONC

Date: July 2, 2013

Re: Under Approved Generic OMB Control No: 0955-0005

ICR Reference No: 19939

The Office of the National Coordinator for Health Information Technology (ONC) is requesting approval for communications testing under Approved Generic OMB Control No. 0955-0005.

The following content and information is provided for your review:

1. Title of Project: Communications Testing for Comprehensive Communication Campaign for HITECH Act – Consumer Survey and Focus Groups

The research includes a survey to be conducted among a total of 2,000 U.S. adult consumers in the following segments:

* U.S. diabetes patients (n=250)
* U.S. cardiovascular disease patients (n=250)
* U.S. cancer patients/cancer survivors (n=250)
* U.S. caregivers (those who provide care and/or make healthcare decisions for at least one adult) (n=250)
* U.S. parents of at least one child under age 18, living in the household (n=500)
* U.S. adults ages 65+ (Medicare beneficiaries) (n=500)

The research also includes six focus group sessions to be conducted among a total of 54 U.S. adult consumers in the following segments:

* U.S. diabetes patients (n=9)
* U.S. cardiovascular disease patients (n=9)
* U.S. cancer survivors (n=9)
* U.S. caregivers (those who provide care and/or make healthcare decisions for at least one adult) (n=9)
* U.S. parents of at least one child under age 18, living in the household (n=9)
* U.S. adults ages 65+ (Medicare beneficiaries) (n=9)

The survey and focus groups will explore awareness, understanding, and attitudes related to the use of electronic health records (EHRs) and other forms of health IT as the nation transitions to a nationwide health IT infrastructure. The focus groups will also test concepts for videos that are being developed to inform the public about Blue Button, a technology that enables patients and consumers to get online access to view their own personal health information, such as their insurance claims and medical records.

1. Control Number: 0955-0005, expiration date 07/31/2014.
2. Public affected by this Project:

Survey:

* U.S. diabetes patients (n=250)
* U.S. cardiovascular disease patients (n=250)
* U.S. cancer patients/cancer survivors (n=250)
* U.S. caregivers (those who provide care and/or make healthcare decisions for at least one adult) (n=250)
* U.S. parents of at least one child under age 18, living in the household (n=500)
* U.S. adults ages 65+ (Medicare beneficiaries) (n=500)

Focus Groups:

* U.S. diabetes patients (n=9)
* U.S. cardiovascular disease patients (n=9)
* U.S. cancer survivors (n=9)
* U.S. caregivers (those who provide care and/or make healthcare decisions for at least one adult) (n=9)
* U.S. parents of at least one child under age 18, living in the household (n=9)
* U.S. adults ages 65+ (Medicare beneficiaries) (n=9)

1. Time needed per Response:

Based on the assumption that the average length of screening for the survey will be 3 minutes per participant, the burden hours associated with 8,000 screening participants is 400 hours (3 minutes x 8,000 = 24,000 minutes = 400 hours).

Based on the assumption that the average length of the survey will be 20 minutes per participant, the burden hours associated with 2,000 survey participants is 667 hours (20 minutes x 2,000 = 40,000 minutes = 667 hours).

Based on the assumption that the average length of screening for the focus groups will be 5 minutes per participant, the burden hours associated with 216 screening participants is 18 hours (5 minutes x 216 = 1,080 minutes = 18 hours).

Based on the assumption that the average length of the focus groups will be 90 minutes per participant, the burden hours associated with 54 focus group participants is hours (90 minutes x 54 = 4,860 minutes = 81 hours).

**Total burden hours associated with the data collection is 1,166 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 |
| Survey among 2,000 consumers | 2,000 | 1 | 20/60 | 667 |
| Screening for Survey | 8,000 | 1 | 3/60 | 400 |
| Focus groups among 54 consumers | 54 | 1 | 1.5 | 81 |
| Screening for focus groups | 216 | 1 | 5/60 | 18 |
| **Total** | **10,270** | **--** | **--** | **1,166** |

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.

Testing of messages and video concepts by consumer focus groups and a consumer online survey will help ensure that the communication effort supports the Department’s missions under HITECH.

1. Methodology

Objectives:

* Better understand consumers’ awareness, attitudes, and understanding of EHRs and health IT to develop effective messages and materials for communication efforts;
* Explore video concepts to inform the public about Blue Button, a technology that enables patients and consumers to get online access to view their own personal health information, to determine the most effective concept for production;
* Use these insights in the continual development of effective communications;
* Help determine distribution channels to reach the target audience with appropriate messages; and
* Expend limited program resource dollars wisely and effectively.

Methodology, Design and Data Analysis:

**Focus Groups**

*Recruitment and Screening*

ONC will conduct focus groups among 54 adult participants in two locations. 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 two locations in which we will conduct research by local recruiting resources. 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. In most cases, participants will have been pre-screened for common medical conditions, thus reducing the screening burden.

*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 $100 for general consumers. We anticipate the total incentive/travel reimbursement offered to each consumer participant to be $100.

*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.**

**Survey**

ONC proposes the use of an online (i.e., web-based) sampling approach as a complement to the consumer focus groups. The consumer online survey is included as Attachment A. The online survey will seek a panel-based (non-probability) sample of U.S. adults ages 18 and older that has a reasonable degree of diversity in key demographic characteristics such as age, gender, education, and race/ethnicity. While the results will be weighted to the U.S. adult population, ONC does not intend to generalize the results to the overall population or produce precise estimates of population parameters using the survey.

To support implementation of the consumer online survey, ONC would retain Ipsos, a vendor that maintains a preexisting representative national panel.

*Recruitment and Sampling*

The overall sampling frame for the online consumer survey is the panel of individuals previously recruited by Ipsos (i.e., the Ipsos Online Panel) to participate in online surveys. The Ipsos Online Panel is an actively managed research access panel that uses multi-source recruitment to maintain a representative base of respondents. It includes individuals who have volunteered to take part in market research and is extensively profiled to efficiently target respondents.

Ipsos employs a survey router (brand name is Cortex) to manage a sample so that it will be representative of a population. Ipsos follows best-in-class principles to measure and report any selection bias that arises from the use of a router:

* Designated team to manage and monitor the router, made up of Ipsos sampling and methodology experts
* Router management team has final authority over which studies are in the router and any prioritization decisions
* Restricted impact of highly-targeted studies
* Random and priority reallocation is balanced
* Respondents allowed to opt-out of the screening process with no penalty
* Diverse, large number of studies maintained in the router
* Limited number of custom screening questions allowed
* All router studies are reviewed by the router team and removed from the router if necessary
* Key metrics monitored multiple times daily to identify potential performance issues
* Supplier traffic is monitored daily to ensure consistency
* Representativeness and consistency of the router population to the general population is monitored

Panel management protocols include a series of legitimacy checks, including name/address matching using external databases, digital fingerprinting, and TrueSample.  Ipsos utilizes inbuilt criteria such as the exclusion of individuals who repeatedly fail to respond to survey invitations, as well as the use of algorithms to screen out participants who exhibit undesirable survey behavior (e.g., inconsistent response, straight-lining, speeding through, etc.).

*Methods of Collecting Data*

The consumer online survey will be administered to online panels to explore attitudes and experiences regarding electronic health records and health IT.

Ipsos conducts all of its online data collection via websites. Through the sampling process, panelists are pre-selected to answer a certain survey; the surveys are not “open access” (i.e., respondents are not self-selected), and respondents do not know the survey content. Panelists receive an invitation email with the following information:

* Survey information (end date, survey number, survey duration, number of incentive points)
* A unique URL that provides access to the questionnaire
* Physical address for Ipsos
* Member support email address
* Link to privacy policy
* Opt-out information

To ensure high quality data, data submitted through the consumer online survey will be subjected to statistical validation techniques, such as disallowing out-of-range values.

All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements.

*Panel Survey Sampling and Methods to Maximize Response Rates:*

Ipsos’ methodology for maximizing response rates includes the following:

* Targeted recruitment through various “wide net” methodologies (e.g., email campaigns, affiliate networks, banner ads, text ads, search engine, co-registration, offline-to-online, specialized websites)
* Use of a point system to incentivize panelists, along with sweepstakes draws. Points systems are recognized as being the best in class in online market research, as they are seen as a neutral system which does not skew the participation of specific groups of people
* Customized incentives and materials for recruiting special targets such as mothers of babies, age group 55+, etc.
* Continuously testing new recruitment sources and methods
* Use of an internal data quality process that incorporates data quality checks at the survey level to reduce or eliminate random responding, illogical or inconsistent responding, overuse of item non-response, and too rapid survey completion.

*Response Rate and Degree of Accuracy*:

We anticipate a 75% response rate for this survey from among invited participants in the panel.

*Incentives for Participants and Burden:*

To minimize panel attrition, surveys are usually kept short (under 25 minutes in length). For surveys requiring 16 or more survey minutes, survey participation is rewarded with points that can be redeemed for cash or prizes. The survey we are proposing will not exceed 20 minutes, and participants will be offered a small incentive, approximately $3-$5 each. Steps are taken to ensure that panel members are not overburdened with survey requests. The primary sampling rule is to assign no more than one survey per week to members. This level of survey frequency helps to keep panelists engaged as part of the panel.

*Confidentiality, Privacy and Opt-In Details*:

Participation in research is voluntary at the time respondents are asked to join the panel, at the time they are asked to participate in any particular survey, and at the time they answer any given question in a survey. Panelists are not coerced to participate in any research and are not removed from the panel as a result of failure to participate in any particular survey project or program of studies. Panelists have the option to ‘opt-out’ of the panel at any time by notifying Ipsos. Ipsos maintains a toll-free phone number and its own call-center panel management facility to receive requests for information and action from panelists.

Survey responses are confidential, with identifying information never revealed without respondent approval. When surveys are assigned to panel members, they receive notice in their password protected e-mail account that the survey is available for completion. Surveys are self-administered and accessible any time of day for a designated period. Participants can complete a survey only once. All panelists, when joining the panel, are given a copy of the Privacy and Terms of Use Policy. The privacy terms are also available electronically at all times to panelists via the panel member website.

*Outcome Reporting*: Preliminary and final summary reports will be provided for the survey and focus groups. Reports will be both descriptive and quantitative in nature. Findings will be used to develop and modify messages and videos to respond to the needs of the ONC constituencies. The information to be collected is not designed or intended to support regulatory decision-making by HHS.

1. Federal Costs: $125,000
2. Requested Approval Date: July 16, 2013
3. Research Instruments:
   1. Survey questionnaires for consumer survey (attachment A)
   2. Screeners for focus groups (attachment B)
   3. Moderator’s guide for focus groups (attachment C)
   4. Video concept #1 - ONC\_ConsumerPSAStoryboard8.4A\_Balloon.pdf (attachment D)
   5. Video concept #2 - ONC\_ConsumerPSAStoryboard8.4A\_Files.pdf (attachment E)
   6. Video concept #3 - ONC\_ConsumerPSAStoryboard8.4A\_Testimonial.pdf (attachment F)