



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

January 30, 2021

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 Conduct Cognitive Testing of Test Survey Questions

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 cognitive testing under Approved Generic OMB Control No. 0990-0376. Specifically, OCPO requests approval to conduct cognitive testing to evaluate questions from the proposed information collection entitled, "Consumer Survey of Attitudes Toward the Privacy and Security Aspects of Electronic Health Records and Electronic Health Information Exchange"

The specific cognitive testing methods proposed for coverage by Approved Generic OMB Control No: 0990-0376 are described below. For more information regarding the proposed information collection entitled, "Consumer Survey of Attitudes Toward the Privacy and Security Aspects of Electronic Health Records and Electronic Health Information Exchange" please refer to the package currently under review, OMB No. TBD, ICR No. TBD.

Public Affected by this Project

Consumers: Because education on Health Information Privacy in a variety of languages is mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, Sec. 13403, we are proposing to conduct cognitive testing among general adult consumers who speak Spanish and/or English. In addition, the socio-demographic characteristics of the target population of the proposed information collection includes expected oversampling of African-Americans and Latinos, which will be also be taken into account in the selection of participants for cognitive testing.

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 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.”

Cognitive Testing Methodology

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. The purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative. The cognitive testing activities will be conducted by NORC at the University of Chicago).

Cognitive testing will be conducted with as many as 25 adults (aged 18 years and older); the cognitive interviews are estimated to be 90 minutes in length, and will be conducted at NORC facilities. The cognitive interviews are designed to uncover difficulties in comprehension, wording, or reporting in the English and Spanish versions of the instrument. Participants from different demographic segments will be recruited by a focus group facility in the Chicago area. Professional recruiters from the facility will call potential participants from the existing opt-in database of local residents that they maintain. Attachment 1 contains the Participant Recruitment Screener for Cognitive Interviews that will be used by the facility to recruit participants. The socio-demographic characteristics of the target population, including the expected oversampling of African-Americans and Latinos, will be considered in the selection of participants. Native Spanish-speaking respondents will also be recruited for the Spanish cognitive interviews. No respondent names or contact information collected during this screening process will be provided to NORC. Interested participants will be assigned a unique numeric identifier and asked to schedule an in-person appointment at NORC’s offices. Attachment 2 contains the Draft Survey Questionnaire with Verbal Consent Script and Cognitive Probes that will be used at the time of

the respondents' appointment. Respondents will first be read the verbal consent script, which describes the purpose of the interview, assures the respondent that their information will be kept confidential, and that they can skip any question they don't wish to answer. Consenting respondents will then complete the draft survey questionnaire with an NORC survey methodologist. The interviews will be conducted at NORC's offices over the telephone, with the respondent and methodologist in separate rooms, in order to simulate the expected main survey data collection mode. After completing the survey, respondents will be asked to participate in a one-on-one in-person debriefing with the NORC survey methodologist to discuss the survey questionnaire items. The debriefing will be used to assess the participants' comprehension of individual questionnaire items, including question intent and the meaning of specific words and phrases. It will also examine any memory retrieval issues, identify the decision processes involved with answering the question, and assess the appropriateness of response categories. During the debriefing, the survey methodologist will ask follow-up questions to specific questionnaire items by administering the cognitive interview probes listed under the relevant questions in Attachment 2. Neither the draft questionnaire nor the cognitive interview protocol will collect any identifying information. The Draft Survey Questionnaire with Verbal Consent Script and Cognitive Probes will be translated into Spanish and administered to the Spanish speaking respondents by a native Spanish speaking NORC survey methodologist. This cognitive testing effort will enable OCPO to gather feedback from respondents on relevant questionnaire items and sections and help uncover a range of potential issues, thereby providing confidence on which issues are the most salient to address prior to fielding the survey. The cognitive interviews will also provide information on the average administration time of the draft survey in order to possibly eliminate items if needed. Following the completion of cognitive testing, any necessary changes to clarify wording and/or question intent will be incorporated into the draft questionnaire.

Explanation of Payments/Gifts to Respondents

As standard practice in commercial market research, and as has been approved by OMB in the past, research study participants will be offered an incentive at a regionally appropriate market rate, which is designed to defer travel costs and babysitting, etc. Participants in the cognitive testing conducted by NORC will receive no more than \$40 for a cognitive interview, which is estimated to be 90 minutes in length. This length of time represents an estimated 10 minutes to describe the cognitive interviewing procedures to the participants and administer verbal consent, plus an estimated 80 minute cognitive interview, including administration of the draft survey followed by the cognitive probes.

Estimates of Burden Hours and Costs

The table below shows the estimated burden for the proposed cognitive testing based on 25 cognitive interviews, estimated to be 90 minutes in length.

Type of Respondent	Number of Responses	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
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Cognitive Testing	25	1	1.5	37.5
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The table below shows the estimated costs for the proposed cognitive testing based on the estimated burden of 37.5 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
Cognitive Testing	37.5	\$30.02	\$1,126

Cost to the Government

The total cost for cognitive testing is \$27,712.

Requested Approval Date: TBD

Attachment 1: Participant Recruitment Screener for Cognitive Interviews

Attachment 2: Draft Survey Questionnaire with Verbal Consent Script and Cognitive Probes

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