

**GENERIC SUB-STUDY SUBMISSION – 0925-0589-06**

**DATE OF REQUEST:** 9/4/2013

**SUB AGENCY (I/C):** NIH/NCI/DCCPS/BRP

**TITLE OF SUB-STUDY:** “Resubmission of Health Information National Trends Survey 4 (HINTS 4) Cognitive Testing of HINTS-FDA Instrument”

**GENERIC CLEARANCE UNDER OMB #0925-0589-06**

**EXP. DATE:** 4/30/2014

<b>TOTAL BURDEN APPROVED:</b>	6,000 hours
<b>BURDEN APPROVED TO DATE:</b>	305 hours
<b>BURDEN FOR THIS REQUEST:</b>	58 hours

**ABSTRACT:**

Cognitive testing of the planned HINTS-FDA questionnaire is essential to identify problems in question wording, context or order effects, as well as response difficulties resulting from the design and layout of the mail form. Although NCI is working towards having a full HINTS-FDA data collection effort (with OMB approval), the results of the proposed cognitive testing will facilitate improvements to both the questions and the design of the questionnaire for use by any Federal agency. The HINTS team has coordinated efforts with other Federal partners to inform the development of the instrument to be tested and has explored CDC’s Q-Bank database of cognitive testing reports (<http://wwwn.cdc.gov/qbank/home.aspx>). Of the 40 tobacco-related items to be tested, 90% of the items are new and have never been included on any other Federal survey. The other 10% (n=4) are modified versions from other surveys and have not been tested or fielded in the proposed form. Participants for the proposed cognitive interviews will be recruited from the non-institutionalized adult household population. Ten of the 35 cognitive interviews will be conducted with adults who speak primarily Spanish at home. All cognitive interviews will be done in person and each will take 90 minutes. A semi-structured protocol for conducting the cognitive interviews will be used which focuses primarily on comprehension issues with those questions new to the HINTS-FDA.

<b>IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?</b> __X__ YES ____ NO ____ N/A	<b>IS PERSONALLY IDENTIFIABLE INFORMATION (PII) BEING COLLECTED?</b> __X__ YES ____ NO ____ N/A
<b>OBLIGATION TO RESPOND:</b> __X__ VOLUNTARY ____ REQUIRED TO OBTAIN OR RETAIN BENEFITS ____ MANDATORY	<b>TYPE OF COLLECTION/RESEARCH?</b> ____ CUSTOMER SATISFACTION ____ USABILITY TESTING ____ FOCUS GROUPS ____ PRETESTING ____ FORMATIVE RESEARCH __X__ QUESTIONNAIRE DEVELOPMENT ____ OTHER: _____
<b>HOW WILL THIS SURVEY BE OFFERED?</b> ____ WEB SITE __X__ TELEPHONE INTERVIEW (screener) ____ MAIL RESPONSE __X__ IN PERSON INTERVIEW (cognitive interviewing) ____ OTHER: _____	
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