

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Reports Clearance Officer, HHS
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SUBJECT: Sub-study, **Smokefree Women Customer Satisfaction Study**, under the Generic “Formative Research, Pretesting, and Customer Satisfaction of NCI’s Communication and Education Resources” (OMB No. 0925-0046)

ASPE received this information collection request under the NIH/NCI Generic approval (OMB No. 0925-0046) on February 7, 2014. Below are ASPE's comments and NCI's responses.

ASPE: Supporting Statement A.4. This section has one sentence stating that there has not been an assessment to date of the four websites. The Department has submitted several tobacco related information collection requests under generic clearances in the past few months, and others are currently under review within the Department. Because of these numerous tobacco related activities, ASPE recommends expanding the information in this section to provide more detail for OMB that will clearly distinguish this submission from others.

NCI might want to add that the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in HHS has reviewed this proposed collection of information, and has determined that it does not duplicate other collections because this ICR is designed to test the specific content of four websites, all of which are targeted to women and all of which were specifically developed as part of the Smokefree program. As a result of the specific characteristics of the respondent population as well as the specific website content, this collection of information is not duplicative of other satisfaction surveys.

NCI RESPONSE: Thank you for your suggestion. The mini-SSA, Section A.4, has been updated to include this language and clarify any duplication efforts with OMB.

ASPE: 2. Privacy Act: Attachments A, C, D, and E reference the Privacy Act, informing participants that the “Rights of study participants are protected by the Privacy Act of 1974.” These attachments need to include the associated Privacy Act System of Records number under which the information from the study participants will be maintained and protected. In addition, the Cover Sheet for the Generic Sub-Study Submission indicates that Personally Identifiable Information is being collected, but this is not specifically stated in section A.10 of the supporting statement under “Assurance of Confidentiality Provided to Respondents.” Instead, section A.10 references “participant information” such as email addresses, which will be de-identified and will later be erased. It appears that the email addresses are the only information collected that is personally identifiable. If the email address is the PII for this study, then this section of Part A should reference the Privacy Act and include the System of Records number and title.

NCI RESPONSE: Thank you for your guidance. The Privacy Act SORN, 09-25-0156 was added to Attachments A, C, D, and E. Additionally, the SORN and PII information were added to the mini-SSA, Section A.10.

ASPE: 3. The Study Landing Page and Consent notes that participants’ “responses will be kept private to the extent allowable by law.” Since this statement on the consent form references the law, (rather than saying something more general to indicate that all possible steps will be taken to protect the privacy of study participants) the law under which the responses will be kept private should be stated. It could be considered as misleading to study participants to state such a protection without explicitly stating the law under which the protection is provided.

NCI RESPONSE: Thank you for your guidance. Rights of study participants are protected by The Privacy Act of 1974, as amended, 5 U.S.C. 552a and information will be kept private under the Privacy Act (SORN #09-25-0156) has been added to the consent form and burden statement under the advisement of the NIH Privacy Act Officer, Karen Pla.

ASPE: 4. Attachment E: It is not clear how the questions in this customer satisfaction survey will actually pinpoint satisfaction (versus behavior) with the specific website content, particularly the variation of content on the four websites. The satisfaction questions #14-21 are general to the website, and although the statements to which participants indicate their extent of agreement include smoking cessation and a healthier lifestyle, there are no statements on smoking cessation and weight management, and this is one of the four websites to be assessed. Questions 17-19 are about frequency of use and not about content. There are no questions that request information on what was most useful, what was of little use, what might be improved, etc. While there is an opportunity for participants to provide comments at the end of the survey, even this is phrased as “please share any suggestions or comments you have for Smokefree Women.” ASPE is concerned that the OMB desk officer will be unable to determine how the

responses to the survey will meet the objectives in the supporting statement on assessing which website stakeholders are most satisfied with and the relevancy of that content for the intended stakeholder population. In anticipation of questions from OMB, can NCI provide some clarification as to how these questions will target satisfaction with specific content for the four websites?

NCI RESPONSE: Thank you for bringing this to our attention. In the mini SSA Justifications we've added the following language in anticipation for OMB questions about satisfaction:

In 2012, TCRB conducted a simple customer satisfaction survey to better understand the stakeholders that were frequenting the website and their smoking behaviors to ultimately tailor the website for the users' needs (OMB No. 0925-0642-12, Approved 5/16/2012). This current survey is to assess which website the stakeholder is most satisfied with as well as the relevancy of the website content for the intended stakeholder population. In order to understand and increase satisfaction of the target population, this study assesses customer satisfaction through the lens of cessation outcomes. Ultimately, we will attempt to better understand cessation outcome measures in relation to participant's attitudes, perceptions, and behaviors. This is based upon the primary purpose of this web-assisted smoking cessation intervention, to help people quit smoking. Ability to achieve this desired outcome may affect customer satisfaction. In order to assess this, a more sophisticated approach to customer satisfaction will be employed within this study.