

Overview of the Change Request for OMB Control No. 0910-0851


Change Request (83-C)





October 18, 2018


The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate edits to the study documents for the upcoming waves of studies under this control number.

The Point of Sale Intervention for Tobacco Evaluation (POSITeV) is a longitudinal survey designed to measure the effectiveness of the CTP point-of-sale campaign that is intended to increase motivation to quit among adult smokers aged 25 to 54. Wave 1 data collection for POSITeV is currently underway and expected to conclude in December 2018. Waves 2, 3, and 4 data collection will be conducted through online or in-person outcome evaluation questionnaires. In addition, an optional app-based (smartphone required) component of the evaluation passively collects the time, date, and store number when a participant visits convenience stores and asks the participant to complete a brief (7 item) questionnaire every 6 months.

List of Revised Study Documents for POSITeV (OMB No. 0910-0851)

OMB Attachment Number	Changes
Attachment_02b_evaluation_questionnaire_Waves_2_3_4  Attachment_02b_evaluation_questionnaire_Waves_2_3_4	<ul style="list-style-type: none">• Added programming and navigation instructions• Renumbered questions to create consistency with Wave 1 questionnaire• Updated some items to accommodate that participants may have quit smoking between waves of data collection• Updated CDC Tips from Former Smokers and Every Try Counts ads• Added a question that asks participants if they have seen an ad that participants are unlikely to have seen to assess false reporting of ad exposure• Updated locator module to confirm contact information for self and close others provided at Wave 1 or obtain this information for the first time if not provided at Wave 1• Added questions about why participants deleted the smartphone app or changed its settings• Added fields for interviewer to specify why participant chose not to download the app• Added questions about phone make and model, operating system, and encryption• Added a question about potential methods of attempting to quit smoking in the future
Attachment_02d_Rationale for Item Changes to Questionnaire Waves 2_3_4	New document

OMB Attachment Number	Changes
 <p>Attachment_02d_Rationale_Im_Change</p>	
 <p>Attachment_02e_Print_Ad_Sample</p>	<p>New document:</p> <ul style="list-style-type: none"> List of statements that will be included in print ads
 <p>Attachment_02f_Still_Try_and_Try_Again_Storyboard</p>	<p>New document:</p> <ul style="list-style-type: none"> Story board for new video ad
Attachment_03b_consent_for_app-based_data_collection	<ul style="list-style-type: none"> Added information about the importance of the app-based portion of the study Added programming to accommodate the number of remaining brief questionnaires based on wave of data collection Changed anticipated data usage from 150MB to 50MB based on new information
Attachment_04d_app-based_notifications_and_messages	<ul style="list-style-type: none"> Added two notification messages regarding permission to access the phone's location Added description of app displayed in Google Play Store and Apple App Store Added a post-holiday message with instructions for downloading and installing the app for those who may have received a new phone over the holidays
Attachment_04e_Wave_2_3_4_POSITev_App_download_instructions	<p>New document:</p> <ul style="list-style-type: none"> Created a new version of the Wave 1 app download instructions (Attachment 4b) for Waves 2, 3, and 4 Provided more detailed instructions than the Wave 1 instructions (Attachment 4b) Removed redundant information from Wave 1 instructions (Attachment 4b)
Attachment_06a_Sorry_I_Missed_You_Card	<ul style="list-style-type: none"> Removed the verbiage about a missed appointment since these cards are often used when trying to make initial contact (back of card is now blank so that field interviewers can handwrite a message specific to the situation)
 <p>Attachment_06b_Notifications_Tracked</p>	<ul style="list-style-type: none"> Adapted language from existing letters to create new versions of the letters that accommodate people who did not understand study procedures and to give the necessary information to persuade potential participants to be in the study Add a lead letter to the existing attachment that can be used to let nonresponse follow-up participants know that someone will be visiting the household

OMB Attachment Number	Changes
Attachment_09d_Invitation_Email_and_Text_for_Waves_2_3_4 	<ul style="list-style-type: none"> Removed text that said that web survey incentives would be paid by digital gift card since they will be paid by check

Attachment_09d_Invitation_Email_and_