

Change Request for OMB Control No. 0910-0915

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 (Outcomes Study)

Expiration Date: 06/30/2026

October 11, 2024

The Food and Drug Administration (FDA or we) is seeking OMB approval of this nonmaterial/non-substantive change request (83-C) to update Supporting Statement Part A, Supporting Statement Part B, survey, and other study documents for OMB Control Number 0910-0915. The purpose of this change request is to update the study documents that will be used in follow-up waves of data collection. The changes described in this request are non-substantive because we are not introducing new concepts or measures that have not received public comment.

Description of Non-Substantive Changes

- 1. The addition of two follow-up waves.** OMB Control Number 0910-0915 is approved to conduct one baseline survey and three follow-up surveys. The purpose and use of this information collection (IC) will help us assess the impact of The Real Cost campaign on tobacco use behavior. We propose adding two additional follow-up waves (follow-up 4 and follow-up 5) to this IC to allow us to follow participants for a longer period of time, as behavior change takes time. Adding a fifth follow-up wave was approved as a non-substantive change request for our prior outcomes study entitled "Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns" (OMB Control Number 0910-0753; March 2022). This change will result in additional burden hours and respondents which is detailed in the "Follow-up Studies Document Roadmap" document submitted as part of this request. No changes will be made to 0910-0915 regarding respondents' recruitment or survey questions (data collection).
- 2. The addition of a second replenishment sample.** OMB Control Number 0910-0915 is approved for one replenishment sample at the follow-up 2 wave. We propose recruiting new participants (i.e., a replenishment sample) at one of the additional waves. The purpose of the replenishment sample is to ensure that we have enough participants, both overall and within the campaign's intended audience age range, to conduct our analyses to assess the impact of the campaign on behavior. This change will result in additional burden hours and respondents which is detailed in the "Follow-up Studies Document Roadmap" document submitted as part of this request. No changes will be made to 0910-0915 regarding respondents' recruitment or survey questions (data collection).
- 3. Expansion of the replenishment sample age range.** OMB Control Number 0910-0915 is approved to recruit a replenishment sample at follow-up 2 wave, with the age range specified as 11-17 years. We propose expanding the age range for this and other replenishment samples to 11-20 years. This age range more closely reflects the age range of the other participants, since participants recruited at baseline are continuing to age. There will be no increase in burden hours due to this change as the sample size will remain the same. No changes will be made to 0910-0915 regarding respondents' recruitment or survey questions (data collection).

The communication materials have been changed to reflect that we will recruit 18- to 20-year-olds for the replenishment waves (Follow Up Waves 2 and 4). FDA has added burden for a fourth and fifth follow-up wave. This resulted in an increase of 39,522 hours. We have a decrease of 220,996 respondents due to a previous reporting error. The new estimated burden for this collection is 154,921 hours and 635,320 respondents. Please see the table below for a summary of the changes.

Overview of Changes to Documents

Document	Description and Justification for Change	Tracked Changes
<p>Supporting Statement Part A</p>	<ol style="list-style-type: none"> 1. Revised to include two new waves of data collection, for a total of five waves of data collection over the study period. <ol style="list-style-type: none"> a. <i>Justification:</i> We plan to extend data collection by adding follow-up 4 (FU4) and follow-up 5 (FU 5) waves. CTP leadership has requested prioritization to assess the impact of The Real Cost campaign on tobacco use behavior. Behavior change happens over time (often over the course of several years), which requires the need for two additional follow-up waves of data collection to enable the longitudinal study sufficient time to assess campaign effects on tobacco use initiation and other tobacco use behaviors. 2. Addition of a replenishment sample to be recruited at follow-up 4. <ol style="list-style-type: none"> a. <i>Justification:</i> The replenishment sample will ensure we have sufficient sample sizes (and therefore, sufficient statistical power) to detect campaign effects of tobacco use behavior. The replenishment sample will also ensure we have a sufficient number of youth in the sample (the intended audience for The Real Cost) given that participants are aging up over time. 3. Revisions to note include that the replenishment sample represents the same age range as the full sample (11 to 20 instead of 11 to 17 as previously planned). <ol style="list-style-type: none"> a. <i>Justification:</i> This change will ensure replenishment samples represent the full age range of the original baseline sample as longitudinal participants age up over time, and will also be consistent with the age range of the supplemental sample, which included participants up to age 20. 4. Revisions to the burden table and annualized cost table. <ol style="list-style-type: none"> a. <i>Justification:</i> Request for additional burden to account for the additional waves of data collection (FU4, FU5) and the addition of a replenishment sample at FU4. 5. Adjusted approximate project schedule. <ol style="list-style-type: none"> a. <i>Justification:</i> Edits to reflect additional waves of data collection. Surveys now estimated to occur from 2023 to 2027. 	 <p>Supporting Statement_A The Real</p>

Document	Description and Justification for Change	Tracked Changes
	<p>6. Updated study personnel.</p> <p>a. <i>Justification:</i> Updated to reflect staffing changes.</p>	
<p>Supporting Statement Part B</p>	<p>1. Revised to include two new waves of data collection, for a total of five waves of data collection over the study period.</p> <p>2. Addition of a replenishment sample to be recruited at FU4.</p> <p>3. Updated study personnel.</p> <p><i>*For justifications of SSB changes, please see justifications for SSA above.</i></p>	 Supporting Statement_BThe Real
<p>Parent Guardian Online Screener: Attachment 2</p>	<p>1. Revisions to programming language to allow for the recruitment of the replenishment samples, ages 11-20 years.</p> <p>a. <i>Justification:</i> To allow for the recruitment of 18-20 year olds as part of the replenishment samples at FU2 and FU4, revisions to the survey programming were made to clarify that an adult member in the household or a youth respondent aged 18 to 20 could complete the online screener.</p> <p>2. Revisions to question measuring participant age.</p> <p>a. <i>Justification:</i> Revision made to improve validity of responses.</p> <p>3. Reordered some items to accommodate survey platform needs and capabilities (e.g., variable VERIFY ROSTER DATA).</p> <p>4. Moved the PRA statement to the body of the document, per OMB guidance.</p>	 Attachment 2: Parent Guardian Online Screenshot  Attachment 2_SPA_FU2.docx
<p>Assent/Consent Document: Attachments 4, 5a, 5b, 6</p>	<p>1. Revised to include a consent form for the replenishment sample respondents that we will recruit aged 18 to 20.</p> <p>2. Added programming language to accommodate longitudinal and replenishment samples.</p>	 Attachment 4: Parent Guardian Permission Letter  Attachment 4: SPA_FU2.docx  Attachment 5a: Youth Assent 11 to 13 ExPEC  Attachment 5a: SPA_FU2.docx

Document	Description and Justification for Change	Tracked Changes
		 Attachment 5b. Youth Assent 14+ ExPECTT :  Attachment 5b. SPA_FU 2docx  Attachment 6. Young Adult Consent ExPECT  Attachment 6. SPA_FU 2docx
Survey: Attachment 9	<ol style="list-style-type: none"> 1. Revisions to age questions and programming language to account for newly recruited participant as part of the replenishment samples (Section A). <ol style="list-style-type: none"> a. <i>Justification:</i> The prior survey version assumed all participants were returning participants, not newly recruited participants. Additional skip logic needed for participants recruited as part of the replenishment sample. 2. Addition of new items and revisions to skip logic to capture tobacco use behavior (Section B). <ol style="list-style-type: none"> a. <i>Justification:</i> We have been asked by our Center leadership to prioritize our assessment of the impact of The Real Cost campaign on tobacco use behavior. As such, we are adding three (B24-B26) additional measures of tobacco use behavior. 3. Updated tobacco product brands listed as examples to reflect current trends in brand popularity (Section B). <ol style="list-style-type: none"> a. <i>Justification:</i> To aid participants' understanding of the specific tobacco products we are asking about, we include introductory text with a description, examples brands, and image of the product. Example brands are updated to reflect current brand popularity. 4. Revisions to existing items to more accurately reflect current campaign content being evaluated (Section E, Section F). <ol style="list-style-type: none"> a. <i>Justification:</i> This study is designed to evaluate the impact of The Real Cost campaign. As such, the survey must measure awareness of current campaign content, and the survey must also include outcome measures related to current content. 	 Attachment 9. Youth Survey ExPECTT 3_FU  Attachment 9. SPA_FU 2docx

Document	Description and Justification for Change	Tracked Changes
	<p>5. Removal of items no longer a priority.</p> <p>a. <i>Justification:</i> To ensure the survey length does not increase.</p> <p>6. Minor revisions to items in Section G: Media Use</p> <p>a. <i>Justification:</i> To ensure valid measurement of participants' media use.</p> <p>7. Revisions to race/ethnicity item.</p> <p>a. <i>Justification:</i> Revised in accordance with guidance from OMB.</p> <p>8. Moved the PRA statement to the body of the document, per OMB guidance.</p>	
<p>Attachments 10 (Text Messages); 15 (E-mail reminder); 23 (Invitation Emails); 25 (Reminder Letter)</p>	<p>1. Revised text messages to add in OMB Co. No. and instructions on how to opt-out of text messages.</p> <p>2. Revisions to procedures to contact participants that are 18+.</p> <p>a. <i>Justification:</i> The replenishment samples will recruit participants age 18-20 years.</p>	 Attachment 10 Text Message Reminder_P  Attachment 15. Email_reminders_ExpE  Attachment 15. SPA_FU2.docx  Attachment 23. Invitation Emails_ExpE  Attachment 25. Reminder Letters_ExpE  Attachment 25_SPA_FU2.docx

Document	Description and Justification for Change	Tracked Changes
<p>Eligibility letters/emails: Attachments 19 and 20</p>	<ol style="list-style-type: none"> 1. Revisions to generate one parental e-mail/letter per selected child as no parent will receive an e-mail or letter noting two children. 2. Revisions to email/letter to notify eligible household members who are 18+ of their eligibility. <ol style="list-style-type: none"> a. <i>Justification:</i> Edits needed to accommodate the recruitment of the replenishment samples, ages 18-20 years. 	<div style="text-align: center;">  Attachment 19: Eligibility Email ExPEC </div> <div style="text-align: center;">  Attachment 19: SPA_FU 2docx </div> <div style="text-align: center;">  Attachment 20: Eligibility Letter ExPEC </div> <div style="text-align: center;">  Attachment 20: SPA_FU 2docx </div>