

**“Evaluation of the Food and Drug Administration's General Market Youth Tobacco
Prevention Campaign”
(OMB Control Number 0910-0753)**

Change Request

April 18, 2017

Overview of the Change Request for OMB Control No. 0910-0753


The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate revisions to the data collection documents for the follow-up 2 wave of data collection for The Real Cost Smokeless campaign that will begin in May 2017. The follow-up data collection will re-contact baseline and follow-up 1 respondents.







We request the following changes to the data collection documents:





- **Follow-Up Survey**
 - Revise the previously OMB-approved follow-up survey instrument to:
 - Bring formatting in line with other *The Real Cost* project surveys
 - Modify items that collect date of birth and location information for clarity
 - Modify programming instructions to incorporate baseline and follow-up 1 data and for clarity
 - Add 2 attention check items
 - Modify fill dates for follow-up 2
 - Remove questions for video and radio ads not on air
 - Add 1 item for internet banner ads
 - Update item response lists to correct typos in previous versions
 - Add 2 end-of-survey items to verify number of surveys and ask for comments from respondents
 - Modify programming to redirect youth 18 and older to new informed consent form
- **Parental Permission and Youth Assent forms**
 - Revise the previously OMB-approved permission and assent forms to:
 - Modify text to reflect 2nd follow-up
 - Remove information about CARI (computer-audio recorded interview, no longer used) in parental permission form
 - Add sentence to inform respondents that answers may be shared with FDA
 - Modify incentive text for clarity
- **Survey reminders and notifications (mail and e-mail)**
 - Revise previously OMB-approved survey invitation/reminder letters and e-mails to:
 - Modify text to reflect follow-up 2
 - Update address and respondent name fills
 - Replace “tobacco use” with “health behaviors” to reduce bias



- Modify the “Sorry I missed You Card” to include contact information for the study
 - Clarify types of incentives
 - Clarify procedures for logging on to the website for the online version
 - Add two new forms
 - Panel maintenance email that mirrors the panel maintenance letter
 - Incentive letter to serve as a receipt for the incentive sent to web respondents
- **New forms to include participants who are 18 years old or older that mirror previously OMB-approved documents for parents of 11 – 17 year old participants**
 - Lead Letter 18
 - Questions and Answers about the Evaluation 18
 - Field Interviewer Verification – 18
 - Survey Invitation Email – 18
 - Email Reminder 1 – 18
 - Email Reminder 2 – 18
 - Email Reminder 3 – 18
 - Panel Maintenance Letter – 18
 - Panel Maintenance Update Form – 18
 - No Response Reminder Letter – 18
 - Panel Maintenance Email - 18

Revised Documents





OMB Attachment #	Change	Rationale
2_R. Youth Followup2 Instrument  Attachment 2_R. Youth Followup 2 Inst	Revise survey template and include programming text	Survey instrument format was edited to align with the template for other FDA CTP studies
	Include pre-survey tutorial	Include tutorial to illustrate flow of survey
	Include permission, assent, and consent forms	Include forms to illustrate flow of survey; these forms include text from attachments 6_R and 24_R
	Add 2 attention check items	Attention check items help verify data validity
	Edit fill dates	Edit to reflect new time frame
	Remove questions for ads	Remove ad questions for ads that are not being aired
	Update template to include specific ad questions	Placeholders were removed and replaced with specific ad questions for clarity
	Add end of survey questions	Add end of survey questions to collect participant feedback and verify number of surveys completed
	Minor text edits to response items	Edit for clarity
6_R. Parent Permission	Remove “[CALCULATE FROM DOB] year-old child	Testing of programmed version returned errors in this form fill that could not be reconciled – DOB not always available some just with age
	Minor text edits	Edit text for clarity









OMB Attachment #	Change	Rationale
 Attachment 6_R. Parent Permission For	Remove CARI text	The RuSTEC team will not use CARI
	Add statement advising participants that information may be shared with FDA	Requested by CTP RIHSC to ensure participants are informed about the use of their data
	Clarify method of payment in the Compensation paragraph	Requested by RTI IRB
	Add permission statement at end of form	Edit to clarify what is being asked
6_R. Youth Assent  Attachment 6_R. Youth Assent (male n	Minor text edits	Edit for clarity
	Add statement advising participants that information may be shared with FDA	Requested by CTP RIHSC to ensure participants are informed about the use of their data
	Add statements advising participants of benefits and physical risks	Requested by CTP RIHSC to ensure all elements of informed consent are clear
10_R. Lead Letter  Attachment 10_R. Lead Letter (male ru	Revise fills	Update to fills is based on available information for participants
	Correct number of participants	Changed number of participating youth to reflect total responses from previous rounds
	Minor text edits	Edit for clarity on how payments will be issued and devises that can be used to access the survey
11_R. Questions and Answers  Attachment 11_R. Questions and Answers	Minor text edits	Edit for clarity
	Remove text referencing the baseline study	Requested by RTI IRB
	Clarify differences in online and in-person study	Requested by RTI IRB
	Clarify method of payment (cash or check)	Requested by RTI IRB
	Correct name of RTI IRB office	Requested by RTI IRB
12_R. Field Interviewer Verification  Attachment 12_R. Field Interviewer Veri	Add question to verify address and adjust numbering for the new question	Verifying the addresses helps RTI staff to identify field interviewer fraud
	Minor text edits	Edit to reflect new time frame
14_R. Notifications  Attachment 14_R. Notifications (male ru	Replace “tobacco use” with “health and health behaviors” throughout	“Tobacco use” was removed from the lead letter and consent forms to reduce response bias. RTI IRB requested that the removal of “tobacco use” be applied to all documents
	Edit address fills	Edit to include contact information obtained from previous surveys



OMB Attachment #	Change	Rationale
	Update “Sorry I missed you” card to include phone number and text edits	Edit for clarity and include study contact information
	Minor text edits	Edit for clarity
15_R. Panel Maintenance Letter  Attachment 15_R. Panel Maintenance Letter	Add fills to include child’s name	First and last name of parents were not mandatory at baseline and may not be available so we are using parent of child’s name
	Minor text edits	Edit for clarity
	Replace “tobacco use” with “health and health behaviors”	“Tobacco use” was removed from the lead letter and consent forms to reduce response bias.
16_R. Panel Maintenance Form  Attachment 16_R. Panel_Maint_Update	Minor text edits	Edit for clarity
18_R. Survey Invitation Email  Attachment 18_R. Survey Invitation Email	Add fills to include child’s name if parent name not available	First and last name of parents were not mandatory at baseline and may not be available
	Clarify method of payment (cash or check)	Requested by RTI IRB
	Remove “Dr.” from project director name	Requested by RTI IRB to make similar across documents
	Add instructions that a parent or guardian must follow the provided steps	Requested by RTI IRB
	Add phone as method of survey completion	Survey personnel clarified that the survey is optimized for phone
19_R. Email_reminder1  Attachment 19_R. Email_Reminder 1 (m	Add fills to include child’s name if parent name not available	First and last name of parents were not mandatory at baseline and may not be available
	Clarify method of payment (cash or check)	Requested by RTI IRB
	Minor text edits	Edit for clarity
	Add instructions that a parent or guardian must follow the provided steps	Requested by RTI IRB
	Add phone as method of survey completion	Survey personnel clarified that the survey is optimized for phone
20_R. Email_reminder2	Add fills to include child’s name if parent name not available	First and last name of parents were not mandatory at baseline and may not be available
	Change 2,000 to 2,200 participants	Additional baseline sample was recruited to correct sampling frame error

OMB Attachment #	Change	Rationale
 Attachment 20_R. Email_Reminder 2 (m	Clarify method of payment (cash or check)	Requested by RTI IRB
	Add instructions that a parent or guardian must follow the provided steps	Requested by RTI IRB
	Minor text edits	Edit for clarity
21_R. Email_reminder3  Attachment 21_R. Email_Reminder 3 (m	Add fills to include child's name if parent name not available	First and last name of parents were not mandatory at baseline and may not be available
	Clarify method of payment (cash or check)	Requested by RTI IRB
	Add instructions that a parent or guardian must follow the provided steps	Requested by RTI IRB
	Minor text edits	Edit for clarity

New Documents

OMB Attachment #	Purpose
22_R. Panel Maintenance Email  Attachment 22_R. Panel Maintenance Eri	Email form to mirror mail form to ensure all participants are reached between rounds; similar to approved attachment 15_R
23_R. Incentive Letter  Attachment 23_R. Incentive Letter (mak	Provide receipt for web participants
24_R. Consent Forms  Attachment 24_R. Consent Forms 18 (r	Obtain consent from youth participants who have aged up to 18 or older; similar to approved attachment 6_R
25_R. Lead Letter 18  Attachment 25_R. Lead Letter 18 (mae	Lead letter for 18 and older population; similar to approved attachment 10_R
26_R. Questions and Answers about the Evaluation – 18	FAQ form for 18 and older population; similar to approved attachment 11_R

 Attachment 26_R. Questions and Answers	
27_R. Field Interviewer Verification – 18  Attachment 27_R. Field Interviewer Veri	FI verification form for 18 and older population; similar to approved attachment 12_R
28_R. Survey Invitation Email – 18  Attachment 28_R. Survey Invitation Em	Email invitation for 18 and older population; similar to approved attachment 18_R
29_R. Email reminder 1 – 18  Attachment 29_R. Email Reminder 1 - 18	Email reminder 1 for 18 and older population; similar to approved attachment 19_R
30_R. Email reminder 2 – 18  Attachment 30_R. Email Reminder 2 -18	Email reminder 2 for 18 and older population; similar to approved attachment 20_R
31_R. Email reminder 3 – 18  Attachment 31_R. Email Reminder 3 - 18	Email reminder 3 for 18 and older population; similar to approved attachment 21_R
32_R. Panel Maintenance Letter - 18  Attachment 32_R. Panel Maintenance Le	Panel maintenance letter for 18 and older population; similar to approved attachment 15_R
33_R. Panel Maintenance Update Form – 18  Attachment 33_R. Panel Maintenance Uj	Panel maintenance update form for 18 and older population; similar to approved attachment 16_R
34_R. No Response Reminder Letter – 18	Reminder letter for 18 and older population; similar to letter in approved attachment 14_R

 Attachment 34_R. No Response Remind	
35_R. Panel Maintenance Email – 19  Attachment 35_R. Panel Maintenance Er	Panel Maintenance email for 18 and older population; similar to approved attachment 15_R