

Evaluation of the Public Education Campaign on Teen Tobacco (OMB Control No. 0910-0753)

Change Request (83-C)

July 13, 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 fourth follow up round of data collection for the evaluation of the Rural Smokeless Education Campaign (RuSTEC). OMB has previously concurred with the submission of this change request.




This study evaluates *The Real Cost Smokeless*. The campaign is intended to prevent tobacco use among youth ages 12-17 who are experimenting with or are at risk for using smokeless tobacco. RuSTEC is a longitudinal control/intervention study in rural areas.

RuSTEC Follow up 4

Follow up 4 is planned for September 2018. The following revisions will be made to the data collection documents for RuSTEC for Follow up 4:









- Revise the wording in the survey instrument to reflect new campaign creative
- Make minor text edits to reflect 4th follow-up and to add clarity
- Add Attachment 02a_R: Section F Media Questions

List of Revised Study Documents for RuSTEC Study Follow up 4 (OMB No. 0910-0753)

OMB Attachment #	Change	Rationale
Part A ExPECTT RuSTEC (RS FU4)  0910-0753 Part A ExPECTT RuSTEC (RS)	Minor edits	Updates to reflect FU4 data collection
02_R. Youth Follow up 4 Instrument  Attachment 02_R. Youth Follow up Ins	Revise programming / administrative text throughout	Edit for clarity and FU4 data collection
	Remove items that are not needed or useful	Items removed either because the campaign does not cover the topic, they are ceilinged, do not reflect current use patterns, or are not useful
	Delete media items and add placeholders	Media items will be covered in detail in attachment 2a_R
02a_R. Section F Media Questions  Attachment 02a_R. Section F Media Qu	New Document	New document to show media items used in the survey
06_R1. Parent Permission	Minor text edits	Edit text for clarity and new round of data collection

 Attachment 06_R1. Parent Permission Fo		
06_R2. Youth Assent  Attachment 06_R2. Youth Assent (male r	Minor text edits	Edit text for clarity and new round of data collection
10_R. Lead Letter  Attachment 10_R. Lead Letter (male rui	Minor text edit	Edit for clarity and new round of data collection
11_R. Questions and Answers  Attachment 11_R. Questions and Ansv	Minor text edits	Edit for clarity and new round of data collection
12_R. Field Interviewer Verification  Attachment 12_R. Field Interviewer Ve	Minor text edits	Edit for clarity and new round of data collection
14_R. Notifications  Attachment 14_R. Notifications (male r	Minor text edits	Edit for clarity and new round of data collection
15_R. Panel Maintenance Letter  Attachment 15_R. Panel Maintenance	Minor text edits	Edit for clarity and new round of data collection
16_R. Panel_Maint_Update_Form  Attachment 16_R. Panel_Maint_Update	Text edits	Edit for clarity and add privacy information to include cellphone number
19_R. Email_reminder1  Attachment 19_R. Email_Reminder_1 (n	Minor text edits	Edit for clarity and new round of data collection
20_R. Email_reminder2	Minor text edits	Edit for clarity and new round of data collection

 Attachment 20_R. Email_Reminder2 (n)		
21_R. Email_reminder3  Attachment 21_R. Email_Reminder3 (n)	Minor text edits	Edit for clarity and new round of data collection
22_R. Panel Maintenance Email  Attachment 22_R. Panel Maintenance	Minor text edits	Edit for clarity and new round of data collection
 Attachment 22_R. Panel Maintenance	Add privacy information	Clarify privacy text to include cellphone use
24_R. Consent Forms  Attachment 24_R. Consent Forms 18 (r)	Minor text edits	Edit for clarity and new round of data collection
25_R. Lead Letter 18  Attachment 25_R. Lead Letter 18 (male)	Minor text edit	Add CTP RIHSC information and add young adults
26_R. Questions and Answers about the Evaluation – 18  Attachment 26_R. Questions and Ansv	Minor text edits	Edit for clarity, add “young adults,” and new round of data collection
27_R. Field Interviewer Verification – 18  Attachment 27_R. Field Interviewer_Ve	Minor text edits	Edit for clarity and new round of data collection
28_R. Survey invitation email – 18  Attachment 28_R. Survey Invitation_Err	Minor text edit	Edit to add young adults for 18+ population
29_R. Email reminder 1 – 18  Attachment 29_R. Email Reminder 1 - 1	Minor text edits	Edit for clarity, add “young adults,” and new round of data collection
30_R. Email reminder 2 – 18	Minor text edits	Edit for clarity, add “young adults,” and new

 <p>Attachment 30 R. Email Reminder 2 - 1</p>		round of data collection
<p>31_R. Email reminder 3 – 18</p>  <p>Attachment 31 R. Email Reminder 3 - 1</p>	Minor text edits	Edit for clarity and new round of data collection
<p>32_R. Panel Maintenance Letter - 18</p>  <p>Attachment 32 R. Panel Maintenance</p>	Minor text edits	Edit for clarity, add “young adults,” and new round of data collection
<p>33_R. Panel Maintenance Update Form – 18</p>  <p>Attachment 33 R. Panel Maintenance</p>	Minor text edits and update privacy information	Add privacy information to include use of cellphones
<p>34_R. Reminder Letter – 18</p>  <p>Attachment 34 R. No Response Remir</p>	Minor text edits and remove early bird text	Edit for clarity, add “young adult,” new round of data, and to remove early bird text because this reminder letter is sent after early bird is over
<p>35_R. Panel Maintenance Email – 18</p>  <p>Attachment 35 R. Panel Maintenance</p>	Minor text edits	Edit for clarity, young adults, and new round of data collection
	Update privacy text	Update privacy text to include cellphone use
<p>36_R. Post_Card_Reminder_Notice</p>  <p>Attachment 36 R. Post_Card_Reminde</p>	Minor text edit	Add CTP RIHSC number
<p>37_R. Text Message for non-responders</p>  <p>Attachment 37 R. Text Message for Nc</p>	Minor text edit	Edit for clarity and new round of data collection