**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)**

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| **OMB Attachment #** | **Change** | **Rationale** |
| Part A ExPECTT RuSTEC (RS FU4) | Minor edits | Updates to reflect FU4 data collection |
| 02\_R. Youth Follow up 4 Instrument | 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 | 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 |
| 06\_R2. Youth Assent | Minor text edits | Edit text for clarity and new round of data collection |
| 10\_R. Lead Letter | Minor text edit | Edit for clarity and new round of data collection |
| 11\_R. Questions and Answers | Minor text edits | Edit for clarity and new round of data collection |
| 12\_R. Field Interviewer Verification | Minor text edits | Edit for clarity and new round of data collection |
| 14\_R. Notifications | Minor text edits | Edit for clarity and new round of data collection |
| 15\_R. Panel Maintenance Letter | Minor text edits | Edit for clarity and new round of data collection |
| 16\_R. Panel\_Maint\_Update\_Form | Text edits | Edit for clarity and add privacy information to include cellphone number |
| 19\_R. Email\_reminder1 | 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 |
| 21\_R. Email\_reminder3 | Minor text edits | Edit for clarity and new round of data collection |
| 22\_R. Panel Maintenance Email | Minor text edits | Edit for clarity and new round of data collection |
| Add privacy information | Clarify privacy text to include cellphone use |
| 24\_R. Consent Forms | Minor text edits | Edit for clarity and new round of data collection |
| 25\_R. Lead Letter 18 | Minor text edit | Add CTP RIHSC information and add young adults |
| 26\_R. Questions and Answers about the Evaluation – 18 | Minor text edits | Edit for clarity, add “young adults,” and new round of data collection |
| 27\_R. Field Interviewer Verification – 18 | Minor text edits | Edit for clarity and new round of data collection |
| 28\_R. Survey invitation email – 18 | Minor text edit | Edit to add young adults for 18+ population |
| 29\_R. Email reminder 1 – 18 | 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 round of data collection |
| 31\_R. Email reminder 3 – 18 | Minor text edits | Edit for clarity and new round of data collection |
| 32\_R. Panel Maintenance Letter - 18 | Minor text edits | Edit for clarity, add “young adults,” and new round of data collection |
| 33\_R. Panel Maintenance Update Form – 18 | Minor text edits and update privacy information | Add privacy information to include use of cellphones |
| 34\_R. Reminder Letter – 18 | 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 |
| 35\_R. Panel Maintenance Email – 18 | Minor text edits | Edit for clarity, young adults, and new round of data collection |
| Update privacy text | Update privacy text to include cellphone use |
| 36\_R. Post\_Card\_Reminder\_Notice | Minor text edit | Add CTP RIHSC number |
| 37\_R. Text Message for non-responders | Minor text edit | Edit for clarity and new round of data collection |