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

**Change Request (83-C)**

**November 1, 2017**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate edits to the study documents for two information collections under this control number: the Rural Smokeless Tobacco Education Campaign evaluation (RuSTEC) and the Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT). These information collections evaluate both *The Real Cost* and *The Real Cost Smokeless*. RuSTEC is a longitudinal control/intervention study in rural areas and has completed 3 rounds of data collection (baseline and 2 follow ups) to date. ExPECTT is a longitudinal nationally representative study which has completed 5 rounds of data collection (baseline and 4 follow ups) with its first cohort, and is now in preparations to recruit a second cohort for the next phase of the evaluation. OMB has concurred with the submission of this change request.

The purpose of this change request is to:

* Update the documents for the third follow up round of data collection for RuSTEC
* Request an increase in burden for RuSTEC Follow up 3
* Add an additional wave of data collection (fourth follow up) to RuSTEC
* Update the documents for the first round of data collection for the second cohort of ExPECTT

## RuSTEC Follow up 3

Follow up 3 is planned for January 2018. Due to high retention rates, we are requesting an additional 146 annualized burden hours to complete Follow up 3.

| **OMB Attachment #** | **Change** | **Rationale** |
| --- | --- | --- |
| 1. SS Part A | Update burden and add 4th follow-up | Additional burden needed because of large response rate and additional follow-up because of delayed campaign launch |
| 2. SS Part B | Update number of expected completes add 4th follow-up | Text edits to include adjusted completes and fourth follow-up |
| 2\_R. Youth Follow up 3 Instrument | Revise programming /administrative text throughout | Edit for clarity and FU3 data collection |
| Update example photos of tobacco products | Change example photos to include current tobacco products |
| Add items to measure awareness of smokeless tobacco use consequences | New advertisements are targeting different health consequences of smokeless tobacco use |
| 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 |
| Add influencer question | Item added to determine how influential celebrities affect behavior |
| Add media items and delete media items not use | Add and delete media items to collect data on current advertising |
| 6\_R1. Parent Permission | Minor text edits | Edit text for clarity and new round of data collection |
| 6\_R2. Youth Assent | Minor text edits | Edit text for clarity and new round of data collection |
| 10\_R. Lead Letter | Minor text edits | 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 |
| Add RTI logo | Add logo to identify study to longitudinal participants |
| 14\_R. Notifications | Minor text edits | Edit for clarity and new round of data collection |
| 16\_R. Panel\_Maint\_Update\_Form | Add request for permission to use text messages | Texting participants to set up interview appointments has improved response rates in other studies |
| 18\_R. Survey Invitation Email | Minor text edits | Edit for clarity |
| 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 | Remove references to early bird incentive | Email will be sent after early bird expires |
| 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 request for permission to use text messages | Texting participants to set up interview appointments has improved response rates in other studies |
| 26\_R. Questions and Answers about the Evaluation – 18 | Minor text edits | Edit for clarity and new round of data collection |
| 29\_R. Email reminder 1 – 18 | Minor text edits | Edit for clarity and new round of data collection |
| 30\_R. Email reminder 2 – 18 | Minor text edits | Edit for clarity 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 and new round of data collection |
| 33\_R. Panel Maintenance Update Form – 18 | Add request for permission to use text messages | Texting participants to set up interview appointments has improved response rates in other studies |
| 35\_R. Panel Maintenance Email – 18 | Minor text edits | Edit for clarity and new round of data collection |
| Add request for permission to use text messages | Texting participants to set up interview appointments has improved response rates in other studies |
| 36\_R. Post\_Card\_Reminder\_Notice | New form | Post card to remind participants to complete the survey in an effort to maintain high level of response rates |
| 37\_R. Text Message for non-responders | New form | Text for Field Interviewers to use to send text messages to non-responding participants in an effort to maintain high level of response rates |

## RuSTEC Follow up 4

We also seek approval to add a fourth follow-up to the RuSTEC study due to a problem encountered by the media buying company at the start of the campaign, which reduced the level of advertising that occurred during that time. To make up for this lapse in potential exposure of the target audience to the campaign, an additional round of data collection is needed. We request an additional 359 annualized burden hours to complete this additional round of data collection.

| **OMB Attachment #** | **Change** | **Rationale** |
| --- | --- | --- |
| 2\_R. Youth Follow up 4 Instrument | Update programming and skip patterns | Update for fourth follow up |

## ExPECTT Cohort 2, First Wave

Documents for the ExPECTT survey were updated in the extension of the overarching control number approved 09/13/16. The next round of data collection is planned for May 2018.

| **Document Name** | **Change** | **Source Document, Source Approval Date** |
| --- | --- | --- |
| 2\_E2a. Youth Baseline Instrument | Edits to advertisements, KABs and tobacco. | Based on Attachment 2\_E2a. Approved 9/13/16 |
| 3\_E2a. Screener Tablet Parent Guardian | Added language about a quality control system.  Added a question about: household race, internet access, SNAP. Deleted questions: e-cig use. Changed: Call the Field Director to Call the ExPECTT project assistance line and added the words: toll free number. | Based on Attachment 3\_E2a. Approved 9/13/16 |
| 3\_E2b1. Screener Mail Parent Guardian A | Reduced and reworded original question, added 3 questions to encourage response. Reformatted for clarity. | Based on Attachment 3\_E2b. Approved 9/13/16 |
| 3\_E2b2. Screener Mail Parent Guardian B | Same as Screener A except for the additional questions. Reformatted for clarity. | Based on Attachment 3\_E2b. Approved 9/13/16 |
| 3\_E2c. Parent/Guardian Instrument | Changes on media questions. Added some questions on current tobacco use status and household tobacco use. Added some language for clarity. | Based on Attachment 2\_E2c. Approved 9/13/16 |
| 3\_E2d. Screener Reminder Letter | New Document | New document |
| 3\_E2e. Screener Reminder Postcard | New Document | New document |
| 6\_E2b1. Permission Parent Baseline | Added information about sample size, information about the selection of youth, clarity about interaction with interviewer, about privacy and future contact. | Based on Attachment 6\_E2b. Approved 9/13/16 |
| 6\_E2b2. Permission Parent Follow-up | Edited information regarding when the contact is taking place, incentive, future contacts and early bird dates. | Based on Attachment 6\_E2b. Approved 9/13/16 |
| 6\_E2c. Assent Youth | Updated info on sample size, time of survey, incentive, toll free number and information about calling the call line. | Based on Attachment 6\_E2c. Approved 9/13/16 |
| 6\_E2d. Consent Youth 18+ 3rd Follow-up | Updated info on sample size, time of survey, incentive, toll free number and information about calling the call line. | Based on Attachment 6\_E2d. Approved 9/13/16 |
| 6\_E2e. Parent Guardian Consent | Added language about a quality control system, toll free number and information about calling the call line and a question to agree. | Based on Attachment 6. Approved 10/13 |
| 8\_E2. Study Description | Updated research study contact information for participants. | Based on Attachment 8\_E2. Approved 9/13/16 |
| 9. Privacy and Data Security | Slight editing changes. Added descriptions on USERID, privacy info on the CARI privacy control statement, | Based on Attachment 9. Approved 9/13/16 |
| 10\_E2a. Lead Letter Baseline | Update approved lead letter to for newly recruited participants. | Based on Attachment 10\_E2. Approved 9/13/16 |
| 10\_E2b. Lead Letter 1st and 2nd Follow-up | Update approved lead letter for follow ups for first and second follow up waves | Based on Attachment 10\_E1. Approved 9/13/16 |
| 10\_E2c. Lead Letter 3rd Follow-up | Update approved lead letter for third and final wave of data collection | Based on Attachment 10\_E1. Approved 9/13/16 |
| 11\_E2. Q & A’s about the ExPECTT Evaluation | Updated research study contact information for participants. | Based on Attachment 11\_E2. Approved 9/13/16 |
| 12\_E2. Telephone Verification Survey | Programing language added in for clarity. | Attachment 12\_E2. Telephone Verification Survey. Approved 9/13/16 |
| 18\_E2a. Survey Invitation Email 1st and 2nd Follow-up | Updated research study contact information for participants. Added in Fill in Field for Early Bird Date. | Based on Attachment 19\_E1. Approved 9/13/16 |
| 18\_E2b. Survey Invitation Email 3rd Follow-up | Updated research study contact information for participants. Added in Fill in Field for Early Bird Date. | Based on Attachment 18\_E1. Approved 9/13/16 |
| 19\_E2a. Email Reminder 1 1st and 2nd Follow-up | Updated research study contact information for participants. | Based on Attachment 19\_E1. Approved 9/13/16 |
| 19\_E2b. Email Reminder 1 3rd Follow-up | Updated research study contact information for participants. | Based on Attachment 19\_E1. Approved 9/13/16 |
| 20\_E2a. Email Reminder 2 1st and 2nd Follow-up | Updated research study contact information for participants. | Based on Attachment 20\_E1. Approved 9/13/16 |
| 20\_E2b. Email Reminder 2 3rd Follow-up | Updated research study contact information for participants. | Based on Attachment 20\_E1. Approved 9/13/16 |
| 21\_E2a. Email Reminder 3 1st and 2nd Follow-up | Updated research study contact information for participants. Updated wording for current wave of data collection. | Based on Attachment 21\_E1. Approved 9/13/16 |
| 21\_E2b. Email Reminder 3 3rd Follow-up | Updated research study contact information for participants. Updated wording for current wave of data collection. | Based on Attachment 21\_E1. Approved 9/13/16 |