

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  1 Part A ExPECTT RuSTEC_TC.docx	Update burden and add 4 th follow-up	Additional burden needed because of large response rate and additional follow-up because of delayed campaign launch
2. SS Part B  2. Part B ExPECTT RuSTEC_TC.docx	Update number of expected completes add 4 th follow-up	Text edits to include adjusted completes and fourth follow-up
2_R. Youth Follow up 3 Instrument  Attachment 2_R. Youth Followup 3 Ir	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


OMB Attachment #	Change	Rationale
	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  Attachment 6_R1. Parent Permission Form	Minor text edits	Edit text for clarity and new round of data collection
6_R2. Youth Assent  Attachment 6_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 r	Minor text edits	Edit for clarity and new round of data collection
11_R. Questions and Answers  Attachment 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  Attachment 14_R. Notifications (male r	Minor text edits	Edit for clarity and new round of data collection
16_R. Panel_Maint_Update_Form  Attachment 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  Attachment 18_R. Survey Invitation Email	Minor text edits	Edit for clarity
19_R. Email_reminder1  Attachment 19_R. Email_Reminder1 (n	Minor text edits	Edit for clarity and new round of data collection

OMB Attachment #	Change	Rationale
20_R. Email_reminder2  Attachment 20_R. Email_Reminder2 (n)	Minor text edits	Edit for clarity and new round of data collection
21_R. Email_reminder3  Attachment 21_R. Email_Reminder3 (n)	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  Attachment 22_R. Panel Maintenance	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  Attachment 26_R. QA about the Evaluat	Minor text edits	Edit for clarity and new round of data collection
29_R. Email reminder 1 – 18  Attachment 29_R. Email Reminder 1 - 1	Minor text edits	Edit for clarity and new round of data collection
30_R. Email reminder 2 – 18  Attachment 30_R. Email Reminder 2 -1	Minor text edits	Edit for clarity and new round of data collection
31_R. Email reminder 3 – 18  Attachment 31_R. Email Reminder 3 - 1	Minor text edits	Edit for clarity and new round of data collection
32_R. Panel Maintenance Letter - 18  Attachment 32_R. Panel Maintenance	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

OMB Attachment #	Change	Rationale
 Attachment 33_R. Panel Maintenance		
35_R. Panel Maintenance Email – 18  Attachment 35_R. Panel Maintenance	Minor text edits Add request for permission to use text messages	Edit for clarity and new round of data collection Texting participants to set up interview appointments has improved response rates in other studies
36_R. Post_Card_Reminder_Notice  Attachment 36_R. Post_Card_Reminder	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  Attachment 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  Attachment 2_R. Youth Followup 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

Document Name	Change	Source Document, Source Approval Date
 Attachment 2_E2a. ExPECTT Instrument		
3_E2a. Screener Tablet Parent Guardian  Attachment 3_E2a. Parent Guardian Tab	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  Attachment 3_E2b1. Parent Guardian Ma	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  Attachment 3_E2b2. Parent Guardian Ma	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  Attachment 3_E2c. Parent or Guardian	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  Attachment 6_E2d. Youth Consent 18 ai	New Document	New document
3_E2e. Screener Reminder Postcard  Attachment 6_E2e. Parent Guardian Co	New Document	New document
6_E2b1. Permission Parent Baseline  Attachment 6_E2b1. Parent Permission E	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	Based on Attachment 6_E2b. Approved 9/13/16

Document Name	Change	Source Document, Source Approval Date
 Attachment 6_E2b2. Parent Permission E	contacts and early bird dates.	
6_E2c. Assent Youth  Attachment 6_E2c. Youth Assent under	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  Attachment 6_E2d. Youth Consent 18 a	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  Attachment 6_E2e. Parent Guardian Co	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  Attachment 8_E2. Study Description_T	Updated research study contact information for participants.	Based on Attachment 8_E2. Approved 9/13/16
9. Privacy and Data Security  Attachment 9. E2 Privacy and Data Sec	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  Attachment 10_E2a. Lead Letter EXP ECTT	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  Attachment 10_E2b. Lead Letter EXP ECTT	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  Attachment 10_E2c. Lead Letter EXP ECTT	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	Updated research study contact information	Based on Attachment 11_E2.

Document Name	Change	Source Document, Source Approval Date
<p>ExPECTT Evaluation</p>  <p>Attachment 11_E2. Q&As about the Exf</p>	<p>for participants.</p>	<p>Approved 9/13/16</p>
<p>12_E2. Telephone Verification Survey</p>  <p>Attachment 12_E2. Telephone Verificati</p>	<p>Programing language added in for clarity.</p>	<p>Attachment 12_E2. Telephone Verification Survey. Approved 9/13/16</p>
<p>18_E2a. Survey Invitation Email 1st and 2nd Follow-up</p>  <p>Attachment 18_E2a. Survey_invitation-en</p>	<p>Updated research study contact information for participants. Added in Fill in Field for Early Bird Date.</p>	<p>Based on Attachment 19_E1. Approved 9/13/16</p>
<p>18_E2b. Survey Invitation Email 3rd Follow-up</p>  <p>Attachment 18_E2b. Survey_invitation-en</p>	<p>Updated research study contact information for participants. Added in Fill in Field for Early Bird Date.</p>	<p>Based on Attachment 18_E1. Approved 9/13/16</p>
<p>19_E2a. Email Reminder 1 1st and 2nd Follow-up</p>  <p>Attachment 19_E2a. Email_reminder1_Exf</p>	<p>Updated research study contact information for participants.</p>	<p>Based on Attachment 19_E1. Approved 9/13/16</p>
<p>19_E2b. Email Reminder 1 3rd Follow-up</p>  <p>Attachment 19_E2b. Email_reminder1_Exf</p>	<p>Updated research study contact information for participants.</p>	<p>Based on Attachment 19_E1. Approved 9/13/16</p>
<p>20_E2a. Email Reminder 2 1st and 2nd Follow-up</p>  <p>Attachment 20_E2a. Email_reminder2_Exf</p>	<p>Updated research study contact information for participants.</p>	<p>Based on Attachment 20_E1. Approved 9/13/16</p>
<p>20_E2b. Email Reminder 2 3rd Follow-up</p>  <p>Attachment 20_E2b. Email_reminder2_Exf</p>	<p>Updated research study contact information for participants.</p>	<p>Based on Attachment 20_E1. Approved 9/13/16</p>
<p>21_E2a. Email Reminder 3 1st</p>	<p>Updated research study contact information</p>	<p>Based on Attachment 21_E1.</p>

Document Name	Change	Source Document, Source Approval Date
<p>and 2nd Follow-up</p>  <p>Attachment 21_E2a. Email_reminder3 Exf</p>	<p>for participants. Updated wording for current wave of data collection.</p>	<p>Approved 9/13/16</p>
<p>21_E2b. Email Reminder 3 3rd Follow-up</p>  <p>Attachment 21_E2b. Email_reminder3 Exf</p>	<p>Updated research study contact information for participants. Updated wording for current wave of data collection.</p>	<p>Based on Attachment 21_E1. Approved 9/13/16</p>