**“Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign”**

**(OMB Control Number 0910-0753)**

**Change Request (83-C)**

**November 24, 2015**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate edits for the third follow up for the Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT) and for the baseline data collection for the Rural Smokeless Tobacco Education Campaign (RuSTEC) evaluation, and to modify the dates for the RuSTEC baseline data collection.

Requested Changes for ExPECTT Follow Up 3:

* Create new consent process for youth who are now 18 years old and therefore no longer require parental consent, and update related forms and reminders
* Revise the wording in multiple documents to reflect the new timeframe (third follow up) and update the number of participants to date
* Edit and/or add items in the follow up and media tracking instruments to:
  + reflect planned TRC messaging
  + collect data on e-cigarettes, an emerging product
  + reflect best practices for item (i.e., question) development
  + synchronize with the RuSTEC survey
  + confirm respondent identity (for continued participation in longitudinal study)
* Reduce the length of the Parent Permission form (this will be the fourth time the parents have provided consent)
* Delete questions from the media tracking survey to reduce survey length

Requested Changes for RuSTEC Baseline:

* Revise and update multiple forms and documents from the ExPECTT baseline to reflect the different campaign target, strategy, and messaging, and the different study population
* Add a mail in screener as part of the recruitment process
* Modify the baseline data collection dates from 01/ 2016 – 04/2016 to 12/2015 – 05/2016

In conversations with OMB in the past, we noted that we expected to have non-substantive changes to our instruments based on the development/changes to the campaign creative.

**Contents of the Change Request Package for OMB No. 0910-0753**

**Supporting Statements**

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| OMB Part A | * Added language about instruments tailored for the Male Rural Smokeless Campaign evaluation. * Revised dates of baseline data collection for evaluation of the Male Rural Smokeless campaign. * References to Attachment 6 for the evaluation of the experimenters and non-triers campaign have been changed to reference “Attachments 6a, 6b, 6c and 6d” which is necessary to change the consenting process for youth who are now age 18. * Added $2 incentive for completing household screener |
| OMB Part\_B | Added procedure for mail-in screener for Rural Male Smokeless |

**Documents modified for Follow Up 3 of the Evaluation of the Experimenters and Non-triers Campaign (ExPECTT)**

| **Document** | **Edits** |
| --- | --- |
| Attachment 2\_Youth Follow-up Instrument ExPECTT 3 | Items added and edited |
| Attachment 4\_Media Tracking Instrument ExPECTT 3 | Items removed and edited |
| Attachment 6a\_Routing for Consent ExPECTT 3 | NEW FORM developed to route respondents through the correct consenting process |
| Attachment 6b\_Parent Permission ExPECTT 3 | * Dramatically reduced in length, as this is the fourth time parents will be providing consent to participate. * Updated to reflect new consenting procedures for 18 year olds. * We have added in the programming used to move through the consent process for the sake of clarity. |
| Attachment 6c\_Youth Assent under 18 ExPECTT 3 | Number of participants updated |
| Attachment 6d\_Youth Consent 18 and up ExPECTT 3 | NEW FORM for youth age 18 and older |
| Attachment 10\_Lead Letter\_ExPECTT 3 | Updated to reflect the new time frame. Updated to reflect new consenting procedures for 18 year olds. |
| Attachment 15\_Panel Maintenance Letter ExPECTT 3 | Updated primarily to reflect the new time frame. Some other minor edits to wording. |
| Email\_reminder1\_ExPECTT 3 | Updated to reflect new consenting procedures for 18 year olds. |
| Email\_reminder2\_ExPECTT 3 | Updated to reflect new consenting procedures for 18 year olds. |
| Email\_reminder3\_ExPECTT 3 | Updated to reflect new consenting procedures for 18 year olds. |
| Rationale for Changes to ExPECTT 3 Instrument | New document |
| Rationale for Changes to ExPECTT 3 Media Tracking Instrument | New Document |
| Survey\_invitation\_email\_ExPECTT 3 | Updated to reflect new consenting procedures for 18 year olds. |

**Documents modified for the Baseline Data Collection for the Evaluation of the Male Rural Smokeless Campaign**

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| **Document** | **Edits** |
| Attachment 2\_Youth Baseline Instrument (male rural smokeless) | Updated from ExPECTT to reflect RuSTEC evaluation |
| Attachment 3\_Parent Screener and Instrument (male rural smokeless) | Updated from ExPECTT. We have modified the screener to include questions on the mail screener. |
| Attachment 3a\_Parent Mail\_Screener (male rural smokeless) | NEW FORM developed to screen for qualified participants by mail and collect baseline household demographics for weighting |
| Attachment 6\_Permission Assent Consent (male rural smokeless) | Updated from ExPECTT; modified to reflect study protocol of RuSTEC |
| Attachment 8\_Study Description (male rural smokeless) | Updated from ExPECTT to reflect RuSTEC |
| Attachment 10\_Lead Letter (male rural smokeless) | Updated from ExPECTT to reflect RuSTEC evaluation including study details, incentive, and RTI contact information |
| Attachment 11\_Questions and Answers (male rural smokeless) | Updated from ExPECTT to reflect RuSTEC evaluation |
| Rationale for Changes to ExPECTT 3 Media Tracking Instrument | Outline of changes from ExPECTT baseline |
| Rationale for Changes to Parent Survey (rural male smokeless | Outline of changes from ExPECTT baseline screener |
| Reminder postcard draft (male rural smokeless)\_c | New document |