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

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

**Change Request**

**April 18, 2017**

**Overview of the Change Request for OMB Control No. 0910-0753**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate revisions to the data collection documents for the follow-up 2 wave of data collection for The Real Cost Smokeless campaign that will begin in May 2017. The follow-up data collection will re-contact baseline and follow-up 1 respondents.

We request the following changes to the data collection documents:

* **Follow-Up** **Survey**
  + Revise the previously OMB-approved follow-up survey instrument to:
    - Bring formatting in line with other *The Real Cost* project surveys
    - Modify items that collect date of birth and location information for clarity
    - Modify programming instructions to incorporate baseline and follow-up 1 data and for clarity
    - Add 2 attention check items
    - Modify fill dates for follow-up 2
    - Remove questions for video and radio ads not on air
    - Add 1 item for internet banner ads
    - Update item response lists to correct typos in previous versions
    - Add 2 end-of-survey items to verify number of surveys and ask for comments from respondents
    - Modify programming to redirect youth 18 and older to new informed consent form
* **Parental Permission and Youth Assent forms**
  + Revise the previously OMB-approved permission and assent forms to:
    - Modify text to reflect 2nd follow-up
    - Remove information about CARI (computer-audio recorded interview, no longer used) in parental permission form
    - Add sentence to inform respondents that answers may be shared with FDA
    - Modify incentive text for clarity
* **Survey reminders and notifications (mail and e-mail)**
  + Revise previously OMB-approved survey invitation/reminder letters and e-mails to:
    - Modify text to reflect follow-up 2
    - Update address and respondent name fills
    - Replace “tobacco use” with “health behaviors” to reduce bias
    - Modify the “Sorry I missed You Card” to include contact information for the study
    - Clarify types of incentives
    - Clarify procedures for logging on to the website for the online version
  + Add two new forms
    - Panel maintenance email that mirrors the panel maintenance letter
    - Incentive letter to serve as a receipt for the incentive sent to web respondents
* **New forms to include participants who are 18 years old or older that mirror previously OMB-approved documents for parents of 11 – 17 year old participants**
  + Lead Letter 18
  + Questions and Answers about the Evaluation 18
  + Field Interviewer Verification – 18
  + Survey Invitation Email – 18
  + Email Reminder 1 – 18
  + Email Reminder 2 – 18
  + Email Reminder 3 – 18
  + Panel Maintenance Letter – 18
  + Panel Maintenance Update Form – 18
  + No Response Reminder Letter – 18
  + Panel Maintenance Email - 18

**Revised Documents**

| **OMB Attachment #** | **Change** | **Rationale** |
| --- | --- | --- |
| 2\_R. Youth Followup2 Instrument | Revise survey template and include programming text | Survey instrument format was edited to align with the template for other FDA CTP studies |
| Include pre-survey tutorial | Include tutorial to illustrate flow of survey |
| Include permission, assent, and consent forms | Include forms to illustrate flow of survey; these forms include text from attachments 6\_R and 24\_R |
| Add 2 attention check items | Attention check items help verify data validity |
| Edit fill dates | Edit to reflect new time frame |
| Remove questions for ads | Remove ad questions for ads that are not being aired |
| Update template to include specific ad questions | Placeholders were removed and replaced with specific ad questions for clarity |
| Add end of survey questions | Add end of survey questions to collect participant feedback and verify number of surveys completed |
| Minor text edits to response items | Edit for clarity |
| 6\_R. Parent Permission | Remove “[CALCULATE FROM DOB] year-old child | Testing of programmed version returned errors in this form fill that could not be reconciled – DOB not always available some just with age |
| Minor text edits | Edit text for clarity |
| Remove CARI text | The RuSTEC team will not use CARI |
| Add statement advising participants that information may be shared with FDA | Requested by CTP RIHSC to ensure participants are informed about the use of their data |
| Clarify method of payment in the Compensation paragraph | Requested by RTI IRB |
| Add permission statement at end of form | Edit to clarify what is being asked |
| 6\_R. Youth Assent | Minor text edits | Edit for clarity |
| Add statement advising participants that information may be shared with FDA | Requested by CTP RIHSC to ensure participants are informed about the use of their data |
| Add statements advising participants of benefits and physical risks | Requested by CTP RIHSC to ensure all elements of informed consent are clear |
| 10\_R. Lead Letter | Revise fills | Update to fills is based on available information for participants |
| Correct number of participants | Changed number of participating youth to reflect total responses from previous rounds |
| Minor text edits | Edit for clarity on how payments will be issued and devises that can be used to access the survey |
| 11\_R. Questions and Answers | Minor text edits | Edit for clarity |
| Remove text referencing the baseline study | Requested by RTI IRB |
| Clarify differences in online and in-person study | Requested by RTI IRB |
| Clarify method of payment (cash or check) | Requested by RTI IRB |
| Correct name of RTI IRB office | Requested by RTI IRB |
| 12\_R. Field Interviewer Verification | Add question to verify address and adjust numbering for the new question | Verifying the addresses helps RTI staff to identify field interviewer fraud |
| Minor text edits | Edit to reflect new time frame |
| 14\_R. Notifications | Replace “tobacco use” with “health and health behaviors” throughout | “Tobacco use” was removed from the lead letter and consent forms to reduce response bias. RTI IRB requested that the removal of “tobacco use” be applied to all documents |
| Edit address fills | Edit to include contact information obtained from previous surveys |
| Update “Sorry I missed you” card to include phone number and text edits | Edit for clarity and include study contact information |
| Minor text edits | Edit for clarity |
| 15\_R. Panel Maintenance Letter | Add fills to include child’s name | First and last name of parents were not mandatory at baseline and may not be available so we are using parent of child’s name |
| Minor text edits | Edit for clarity |
| Replace “tobacco use” with “health and health behaviors” | “Tobacco use” was removed from the lead letter and consent forms to reduce response bias. |
| 16\_R. Panel Maintenance Form | Minor text edits | Edit for clarity |
| 18\_R. Survey Invitation Email | Add fills to include child’s name if parent name not available | First and last name of parents were not mandatory at baseline and may not be available |
| Clarify method of payment (cash or check) | Requested by RTI IRB |
| Remove “Dr.” from project director name | Requested by RTI IRB to make similar across documents |
| Add instructions that a parent or guardian must follow the provided steps | Requested by RTI IRB |
| Add phone as method of survey completion | Survey personnel clarified that the survey is optimized for phone |
| 19\_R. Email\_reminder1 | Add fills to include child’s name if parent name not available | First and last name of parents were not mandatory at baseline and may not be available |
| Clarify method of payment (cash or check) | Requested by RTI IRB |
| Minor text edits | Edit for clarity |
| Add instructions that a parent or guardian must follow the provided steps | Requested by RTI IRB |
| Add phone as method of survey completion | Survey personnel clarified that the survey is optimized for phone |
| 20\_R. Email\_reminder2 | Add fills to include child’s name if parent name not available | First and last name of parents were not mandatory at baseline and may not be available |
| Change 2,000 to 2,200 participants | Additional baseline sample was recruited to correct sampling frame error |
| Clarify method of payment (cash or check) | Requested by RTI IRB |
| Add instructions that a parent or guardian must follow the provided steps | Requested by RTI IRB |
| Minor text edits | Edit for clarity |
| 21\_R. Email\_reminder3 | Add fills to include child’s name if parent name not available | First and last name of parents were not mandatory at baseline and may not be available |
| Clarify method of payment (cash or check) | Requested by RTI IRB |
| Add instructions that a parent or guardian must follow the provided steps | Requested by RTI IRB |
| Minor text edits | Edit for clarity |

**New Documents**

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| **OMB Attachment #** | **Purpose** |
| 22\_R. Panel Maintenance Email | Email form to mirror mail form to ensure all participants are reached between rounds; similar to approved attachment 15\_R |
| 23\_R. Incentive Letter | Provide receipt for web participants |
| 24\_R. Consent Forms | Obtain consent from youth participants who have aged up to 18 or older; similar to approved attachment 6\_R |
| 25\_R. Lead Letter 18 | Lead letter for 18 and older population; similar to approved attachment 10\_R |
| 26\_R. Questions and Answers about the Evaluation – 18 | FAQ form for 18 and older population; similar to approved attachment 11\_R |
| 27\_R. Field Interviewer Verification – 18 | FI verification form for 18 and older population; similar to approved attachment 12\_R |
| 28\_R. Survey Invitation Email – 18 | Email invitation for 18 and older population; similar to approved attachment 18\_R |
| 29\_R. Email reminder 1 – 18 | Email reminder 1 for 18 and older population; similar to approved attachment 19\_R |
| 30\_R. Email reminder 2 – 18 | Email reminder 2 for 18 and older population; similar to approved attachment 20\_R |
| 31\_R. Email reminder 3 – 18 | Email reminder 3 for 18 and older population; similar to approved attachment 21\_R |
| 32\_R. Panel Maintenance Letter - 18 | Panel maintenance letter for 18 and older population; similar to approved attachment 15\_R |
| 33\_R. Panel Maintenance Update Form – 18 | Panel maintenance update form for 18 and older population; similar to approved attachment 16\_R |
| 34\_R. No Response Reminder Letter – 18 | Reminder letter for 18 and older population; similar to letter in approved attachment 14\_R |
| 35\_R. Panel Maintenance Email – 19 | Panel Maintenance email for 18 and older population; similar to approved attachment 15\_R |