

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

Change Request (83-C)




July, 27 2017




The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate edits to the study documents for our media tracking survey, which is a component of the evaluation of FDA's public education campaign, *The Real Cost* (TRC), intended to prevent youth tobacco use among youth ages 12-17 who are at risk for smoking cigarettes. The media tracking study is a cross sectional study administered between waves of the outcome evaluation to assess awareness of campaign ads and to understand reach and receptivity of among the target population on an ongoing basis.

Documents for the media tracking survey were updated in the extension of the overarching control number approved 9/13/16, however, no data have been collected since that time using those versions. The next round of data collection is planned for July/August 2017. We would now like to revise the data collection documents for the media tracking survey as follows:

- Separate the media tracking screener into multiple documents, including:
 - o Parent permission
 - o Youth assent
 - o Media tracking screener
- Revise the parent permission and youth assent forms to provide more information about the studies and update a name change for the vendor
- Revise the wording in the survey instrument to reflect:
 - o new campaign creative
 - o changes in youth media use
 - o increased prevalence of other tobacco products (i.e., non-cigarette) among target audience

Tracked changed documents:

| Document | Edits |
|--|---|
| 1. Part A ExPECTT RuSTEC  1 Part A ExPECTT RuSTEC_TC.docx | Minor changes made including: <ul style="list-style-type: none">• Updated file names• Vendor was bought and changed names• Staffing changes at CTP• Updated project schedule |
| 2. Part B ExPECTT RuSTEC  2. Part B ExPECTT RuSTEC_TC.docx | Minor changes made including: <ul style="list-style-type: none">• Updated file names• Vendor was bought and changed names• Staffing changes at CTP |
| Attachment 4_E2a1. Media Tracking Parent Permission  Attachment 4_E2a1. Media Tracking Parer | <ul style="list-style-type: none">• Language removed from the screener document to create a standalone document that details more information about the study for the parents |

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| <p>Attachment 4_E2a2. Media Tracking Youth Assent</p>  <p>Attachment 4_E2a2. Media Tracking Youth</p> | <ul style="list-style-type: none"> • Language removed from the screener document to create a standalone document that details more information about the study for the participants |
| <p>Attachment 4_E2a3. Media Tracking Screener</p>  <p>Attachment 4_E2a3. Media Tracking Scree</p> | <ul style="list-style-type: none"> • Permission and Assent language removed from this document and separated out into the Parent Permission document and Youth Assent document to allow for more clarification on the study and clarification about different audiences • Screener questions remained the same |
| <p>Attachment 4_E2b. Media Tracking Instrument</p>  <p>Attachment 4_E2b. Media Tracking Instru</p> | <p>Instrument was updated to reflect:</p> <ul style="list-style-type: none"> • new ads and their respective belief statements • updated tobacco product use among youth • minor edits were made to reflect current media use trends |