**“Food and Drug Administration’s Evaluation of the Fresh Empire Campaign on Tobacco” (OMB Control Number 0910-0788)**

**Change Request**

**August 11, 2017**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to revise the data collection protocol and documents for the third follow-up data collection for EFECT.

The Evaluation of the Fresh Empire Campaign on Tobacco (EFECT) is designed to measure awareness of and exposure to the campaign and assess its impact on outcome variables of interest. Baseline data collection (July 2015 - November 2015), first follow-up data collection (April 2016 – June 2016), and second follow-up data collection (January – June 2017) were conducted in 15 campaign-targeted cities and 15 comparison cities through in-person and web-based surveys. This change request is to revise the data collection protocol and documents for the third follow-up data collection for EFECT.

In this change request, we request approval to make the following changes to the protocol and data collection documents:

* Revise the wording in multiple documents to reflect the new round of data collection (third follow-up) and timeframe since last survey.
* Adjust burden hours to account for the number of participants to date. No new burden is anticipated as a result of these changes.
* Offer an additional $5 early bird incentive for longitudinal respondents who originally completed an in-person survey to encourage them to complete the web survey.
* Format the post-campaign instrument in a standard template requested by FDA. This template is designed with the intent of being clear and easily-understood by members of the public who may choose to access these documents on reginfo.gov.
* Edit, add, or delete items in the post-campaign instrument to:
  + reflect updated campaign messages and media, such as videos
  + maintain a reasonable survey length
  + clarify instructions and make edits based on mode (web vs. in-person)
  + reflect best practices for item (i.e., question) development

**Contents and tracked documents:**

| **Att #** | **Document** | **Edits** |
| --- | --- | --- |
|  | Supporting Statement Part A | * Updated contact information for individuals consulted for questionnaire development * Added detail about offering an additional $5 “early bird” incentive during the third follow-up data collection period * Revised annualized burden hour estimate to reflect number of participants to date; no new burden resulted from these changes * Revised annualized cost burden estimate to reflect the revised burden hours. * Updated timeline for post-test data collection. |
|  | Supporting Statement Part B | * Clarified that youth who participated in a previous survey wave will be re-contacted at each follow-up wave *up to the age of 18* (no change to study protocol) * Revised to include information about the early bird incentive in data collection procedures * Updated contact information for individuals consulted for questionnaire development |
| 1 | Post Campaign Instrument | * Items added, edited and deleted from post-campaign instrument; see details in “Summary of Changes to EFECT Post-Campaign Instrument” |
| 3 | Outcome Web Screener | * Formatted in a template requested by FDA that is more clear for the public: ASK statements clarify who sees items, and GOTO statements describe skip logic in plain English * Reformatted to clarify programming notes * Changed language from “confidentiality” to “privacy… to the extent allowed by law” * Revised to reflect wave of study and possibility of future contact * Added language for pop-up box if respondent doesn’t enter zip code since this is an important eligibility criteria * Some other minor edits to wording |
| 5a | Parental Permission Youth Assent Longitudinal Age 12-17 Household | * Clarified instructions for interviewers * Clarified that incentive will be cash (no change to study protocol) * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 5b | Informed Consent Longitudinal Age 18 Household | * Clarified instructions for interviewers * Clarified that incentive will be cash (no change to study protocol) * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 5c | Parental Permission Youth Assent Longitudinal Age 12-17 Web | * Revised to reflect wave of the study and possibility of future contact * Clarified that incentive will be a gift card (no change to study protocol) * Added information about early bird incentive * Changed “confidentiality” to “privacy” * Some other minor edits to wording |
| 5d | Informed Consent Longitudinal Age 18 Web | * Revised to reflect wave of the study and possibility of future contact * Clarified that incentive will be a gift card (no change to study protocol) * Added information about early bird incentive * Changed “confidentiality” to “privacy” * Some other minor edits to wording |
| 5e | Youth Assent Cross Sectional Age 15 - 17\_Social Media Web | * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 5f | Youth Assent Cross Sectional Age 13 - 14\_Social Media Web | * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 5g | Youth Assent Longitudinal Age 13 – 17 Social Media Web | * Clarified that incentive will be a gift card (no change to study protocol) * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 5i | Youth Assent Longitudinal Age 15 – 17 Social Media Permission Waived | * Changed “confidentiality” to “privacy” * Revised to reflect wave of the study and possibility of future contact * Some other minor edits to wording |
| 6 | Study Description | * Changed language to “private to the extent allowed by law” for consistency with other documents |
| 8a | Outcome Parent Lead Letter Follow-up 3 | * Clarified that incentive will be a gift card (no change to study protocol) * Added information about early bird incentive * Revised to more clearly explain study procedures and option for online survey * Changed language to “private to the extent allowed by law” for consistency with other documents * Some other minor edits to wording |
| 13 | Unable to Contact Letters | * Revised how letters are addressed * Revised to more clearly explain study procedures and option for online survey * Revised to reflect wave of the study * Changed language to “private to the extent allowed by law” for consistency with other documents * Some other minor edits to wording |
| 14a | Questions and Answers Fact Sheet (Household) | * Removed capitalization from “Privacy” and “Privacy Agreement” |
| 14b | Questions and Answers Fact Sheet (Online) | * Removed capitalization from “Privacy” and “Privacy Agreement” |
| 15 | Interview Incentive Receipt | * Changed “confidentiality” to “privacy” |
| 17 | Verification Call Script Age 13 – 17 | * Retitled this document for use with 13 – 17 year-olds * Corrected question order and numbering |
| 17a | Verification Call Script Age 18 | * NEW document based on previously-approved Attachment 17 that uses language suitable for 18 year-olds by removing references to parental permission |