

**“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:
 - o reflect updated campaign messages and media, such as videos
 - o maintain a reasonable survey length
 - o clarify instructions and make edits based on mode (web vs. in-person)
 - o reflect best practices for item (i.e., question) development

Contents and tracked documents:

Att #	Document	Edits
	<p>Supporting Statement Part A</p>  <p>0910-0788 SS OMB_Part A_FU2_TC</p>	<ul style="list-style-type: none"> - 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.
	<p>Supporting Statement Part B</p>  <p>0910-0788 SS OMB_Part B_FU2_TC</p>	<ul style="list-style-type: none"> - Clarified that youth who participated in a previous survey wave will be re-contacted at each follow-up wave <i>up to the age of 18</i> (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	<p>Post Campaign Instrument</p>  <p>Attachment 1_Post Campaign Instrument</p>	<ul style="list-style-type: none"> - Items added, edited and deleted from post-campaign instrument; see details in “Summary of Changes to EFECT Post-Campaign Instrument”
3	<p>Outcome Web Screener</p>  <p>Attachment 3_Outcome Web Scre</p>	<ul style="list-style-type: none"> - 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	<p>Parental Permission Youth Assent Longitudinal Age 12-17 Household</p>	<ul style="list-style-type: none"> - 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

Att #	Document	Edits
	 Attachment 5a_Parental Permissik	of future contact - Some other minor edits to wording
5b	Informed Consent Longitudinal Age 18 Household  Attachment 5b_Informed Consen	- 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  Attachment 5c_Parental Permissik	- 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  Attachment 5d_Informed Consen	- 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  Attachment 5e_YouthAssent_Crr	- 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  Attachment 5f_YouthAssent_Crc	- 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  Attachment 5g_YouthAssent_Lor	- 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

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5i	Youth Assent Longitudinal Age 15 – 17 Social Media Permission Waived  Attachment 5i_Youth Assent_Longitudinal /	<ul style="list-style-type: none"> - 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  Attachment 6_Study Description_FU3_TC.	<ul style="list-style-type: none"> - Changed language to “private to the extent allowed by law” for consistency with other documents
8a	Outcome Parent Lead Letter Follow-up 3  Attachment 8a_Outcome Parent L	<ul style="list-style-type: none"> - 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  Attachment 13_Unable to Contac	<ul style="list-style-type: none"> - 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)  Attachment 14a_Questions and A	<ul style="list-style-type: none"> - Removed capitalization from “Privacy” and “Privacy Agreement”
14b	Questions and Answers Fact Sheet (Online)  Attachment 14b_Questions and A	<ul style="list-style-type: none"> - Removed capitalization from “Privacy” and “Privacy Agreement”
15	Interview Incentive Receipt  Attachment 15_Interview Incenti	<ul style="list-style-type: none"> - Changed “confidentiality” to “privacy”

Att #	Document	Edits
17	Verification Call Script Age 13 – 17  Attachment 17_Verification Call Sc	<ul style="list-style-type: none"> - Retitled this document for use with 13 – 17 year-olds - Corrected question order and numbering
17a	Verification Call Script Age 18  Attachment 17a_Verification Call Sc	<ul style="list-style-type: none"> - NEW document based on previously-approved Attachment 17 that uses language suitable for 18 year-olds by removing references to parental permission