

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

Change Request

December 20, 2016

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 second 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) and first follow-up data collection (April 2016 – June 2016) were conducted in 15 campaign-targeted cities and 15 comparison cities through in-person and web-based surveys.

Thanks to changes in our protocol approved by OMB in our last change request package, our social media recruitment efforts were more successful during first follow-up than they had been at baseline. As a result, we request changes to the protocol that will discontinue the following recruitment methods:

- 1) Recruitment of youth via a paper screener mailed to sample addresses
- 2) Recruitment of youth in-home by field interviewers
- 3) Recruitment of youth via online screener link sharing (snowball sampling)





These changes to protocol will still allow us to recruit enough new respondents through social media recruitment on Facebook, Twitter and Instagram to account for attrition.








We also request the following changes to the data collection documents:









- Remove references and documents related to discontinued recruitment methods
- Revise the wording in multiple documents to reflect the new wave of data collection (second follow-up) and timeframe since last survey
- Adjust burden hours to account for removal of mail screener option and number of participants to date. No new burden is anticipated as a result of these changes.
- Edit and/or add items in the post-campaign instrument to:
 - o confirm respondent identity (for continued participation in longitudinal study)
 - o clarify instructions and make edits based on mode (web vs. in-person)
 - o reflect updated campaign messages and media, such as videos
 - o reflect best practices for item (i.e., question) development
 - o understand data quality by adding “attention check” items




- Update consent forms to clarify number of participants in each wave, reflect all methods used to date to recruit respondents to the study, and add language to ensure human subjects' protection

Contents of the OMB Package for the Second EFECT Follow-up Survey:

Att #	Document	Edits
	Change request roadmap  0910-0788 Change Request Roadmap.doc	-
	Supporting Statement Part A  0910-0788 SS OMB_Part A_FU2_12	<ul style="list-style-type: none"> - Updated to reflect discontinued recruitment methods during this round (i.e., mailed screener, additional in-home recruitment of siblings, snowball sampling) - Updated individuals consulted for questionnaire development - Updated consent/assent attachments to reference versions applicable to the remaining rounds of data collection (5a, 5b, 5c, 5d, 5e, 5f, 5g, 5i) - Revised annualized burden hour estimate to reflect removal of mail screener option, use of online screener, and number of participants to date. No new burden resulted from these changes; the revised estimate falls below the originally-approved burden hours for this study. - Revised annualized cost burden estimate to reflect the revised burden hours. The revised estimate falls below the originally-approved estimate for this study.
	Supporting Statement Part B  0910-0788 SS OMB_Part B_FU2_12	<ul style="list-style-type: none"> - Updated to reflect the actual and anticipated participants recruited through social media platforms - Updated to reflect discontinued recruitment methods (i.e., mailed screener, additional in-home recruitment of siblings, snowball sampling) - Updated references to consent/assent attachments - Updated individuals consulted for questionnaire development
1	Post Campaign Instrument  Attachment 1_Post Campaign Instrument	<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	Outcome Web Screener	<ul style="list-style-type: none"> - Revised programming notes - Updated to remove discontinued recruitment methods (i.e., in-home recruitment of siblings) - Edited instructions for selecting pictures to make the

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	 Attachment 3_Outcome Web Scre	survey user-friendly - Included language about each respondent being able to take the survey only once - Some other minor edits to wording
3a	Social Media Ad  Attachment 3a_Social_Media_Ad	- Changed “earn \$25” to “get \$25” - Updated to include Instagram advertisement - Note: no tracked changes version
5a	Parental Permission Youth Assent Longitudinal Age 12-17 Household  Attachment 5a_Parental Permissi	- Revised to more clearly explain study procedures and respondent rights - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording
5b	Informed Consent Longitudinal Age 18 Household  Attachment 5b Informed Consent_Lc	- Revised to more clearly explain study procedures and respondent rights - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording
5c	Parental Permission Youth Assent Longitudinal Age 12-17 Web  Attachment 5c_Parental Permissi	- Revised to more clearly explain study procedures and respondent rights - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording
5d	Informed Consent Longitudinal Age 18 Web  Attachment 5d_Informed Consen	- Revised to more clearly explain study procedures and respondent rights - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording
5e	Youth Assent Cross Sectional Age 15 - 17_Social Media Web	- Revised to more clearly explain study procedures and respondent rights - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording

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	 Attachment 5e_Youth Assent_Cr	
5f	Youth Assent Cross Sectional Age 13 - 14_Social Media Web  Attachment 5f_Youth Assent_Crc	- NEW FORM for new youth age 13 – 14 who are recruited by social media for web survey
5g	Youth Assent Longitudinal Age 13 – 17 Social Media Web  Attachment 5g_Youth Assent_Loi	- NEW FORM for longitudinal youth age 13 – 17 who were originally recruited by social media
5i	Youth Assent Longitudinal Age 15 – 17 Social Media Permission Waived  Attachment 5i_Youth Assent_Longitudinal	- NEW FORM for longitudinal youth age 15 – 17 who were originally recruited by social media and have parental permission waived
6	Study Description  Attachment 6_Study Description_TRACKE	<ul style="list-style-type: none"> - Updated to reflect time for post-test survey - Updated contact information for study team - Some other minor edits to wording
8a	Outcome Parent Lead Letter Wave 3  Attachment 8a_Outcome Parent L	<ul style="list-style-type: none"> - Revised to reflect wave of the study - Updated contact information for study team - Some other minor edits to wording
13	Unable to Contact Letters  Attachment 13_Unable to Contac	<ul style="list-style-type: none"> - Revised to more clearly explain study procedures for consent and option for online survey - Updated contact information for study team - Some other minor edits to wording
14a	Questions and Answers Fact Sheet	- Revised to reflect timeframe since initial contact and interview

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	 Attachment 14a_ Questions and A	<ul style="list-style-type: none"> - Updated contact information for study team - Some other minor edits to wording
14b	Questions and Answers Fact Sheet  Attachment 14b_ Questions and A	<ul style="list-style-type: none"> - Revised to more clearly explain study procedures for web survey. - Updated to reflect time for post-test survey - Updated contact information for study team - Some other minor edits to wording.