





**Evaluation of the FDA's General Market Youth Tobacco Prevention Campaigns (OMB Control No. 0910-0753)**











**Change Request (83-C)**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate edits to the instrument for one information collection under this control number: the Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT). OMB granted email approval on 12/26/18 considering the government shutdown. This version amends the change request approved by OMB on. To include the remaining documents and the additional questions in the youth instrument

The purpose of this change request is to:

- Update the survey instrument for the first round of data collection for the second cohort of ExPECTT.
  - Based on new creative that focuses on flavoring in e-cigarettes, the study now incorporates questions related to use of flavored e-cigarette products
  - Spanish-language questions were removed
  - Questions E3, E5, E13 and E15 have been updated to reflect the planned advertisements
  - Frequency of show programming and platform questions were deleted
  - Additional cessation outcome questions have been deleted
  - Question A1\_2 related to birthdate was updated for quality control purposes
  - F5 and F6 was updated to reflect platforms and locations
  - Main message questions were updated to reflect planned advertisements

#	Document	Edits
2_E2b	Youth Instrument  Attahment 2_E2b. Youth Follow-up 11	Updated to reflect changes to advertisement, the placement of advertising related to video games and prior data analysis of age verification question
6_E2b3	Parent Permission form  Attahment 6_E2b3 Parent Permission E:	Edits for clarity and to reflect methods used at follow-up, which differ from those used at baseline. Revised to reflect the incentive amount and contact information. Added a request for contact information.
6_E2c2	Youth Assent form  Attahment 6_E2c2 Youth Assent Under	Revised to reflect the expected sample size for data collection and the incentive amount. Added info for the project assistance line.
8_E2a	Study Description  Attahment 8_E2a Study description.d	Edits for clarity; Revised to reflect the incentive amount. Added info for the project assistance line.
10_E2d	Lead Letter for the 1 <sup>st</sup> and 2 <sup>nd</sup> follow-up	Edits for clarity; Revised to reflect the expected sample size for data collection, the incentive amount and new study director.

	 Attachment 10_E2d Lead Letter ExPECTT	
11_E2a	<b>Study Q &amp; A</b>  Attachment 11_E2a Q&As about the ExF	Edits for clarity; Added info for the project assistance line.
12_E2a	<b>Telephone Verification Survey</b>  Attachment 12_E2a Telephone Verificati	This document was not approved as part of this (ExPECTT Cohort II) study, but was approved in this form for the ExPECTT Cohort I study.
13_E2a	<b>Notifications</b>  Attachment 13_E2a Notifications ExPEC	Edits for clarity; Removed the letter "Screening - Unable to Contact" since we are done with screening.
15_E2a	<b>Panel Maintenance Letter</b>  Attachment 15_E2a Panel Maintenance	Added info for the project assistance line.
18_E2c	<b>Survey Invitation Email</b>  Attachment 18_E2c Survey Invitation Em	Revised to reflect the incentive amount. Added info for the project assistance line. Revised study director name.
19_E2d	<b>Email reminder #1</b>  Attachment 19_E2d Reminder_Email 1 Ex	Edits for clarity; Revised to reflect the incentive amount. Added info for the project assistance line. Revised study director name.
20_E2c	<b>Email reminder #2</b>  Attachment 20_E2c. Email_reminder2 ExF	Edits for clarity; Revised to reflect the incentive amount. Added info for the project assistance line. Revised study director name.
21_E2c	<b>Email reminder #3</b>  Attachment 21_E2c Email Reminder 3 Ex	Edits for clarity; Revised to reflect the incentive amount. Added info for the project assistance line. Revised study director name.
22	<b>Reminder Letter</b>  Attachment 22. Reminder Letter Exp	This is a new document, necessary to contact those who did not provide an email address.