

National Panel of Tobacco Consumer Studies (OMB Control Number 0910-0815)

Change Request (83-C)

April 21, 2017

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate several non-substantive changes to the protocol, tablet consent, and enrollment questionnaire based on experiences in the field.

Overview of the Change Request

Since January 2017, national screening, recruitment, and enrollment efforts for the National Panel of Tobacco Consumer Studies (OMB # 0910-0815) have been under way. To date, a total of 1,809 panel members have been enrolled. There is no change in the burden estimate included in the original clearance request.

CTP is establishing a panel of 4,000 adult tobacco users. To minimize the potential for coverage and nonresponse bias, we had planned to enroll in the panel 3,200 participants via web mode (using a personal device), a maximum of 400 participants via mail mode, and a maximum of 400 participants via loaned study-provided tablet based on estimates of Internet access from the 2014 Health Information National Trends Survey (HINTS). We are requesting an increase in the maximum number of participants who can enroll in the panel via mail mode from 400 to 800. The total number of participants enrolled in the panel will remain at 4,000.

Of the 1,809 panel members enrolled to date, 1,454 (80%) have enrolled as web mode participants and 355 (20%) have enrolled as mail mode participants. The percentage of panel members enrolling via mail mode is higher than the 10% rate we estimated originally. This is due in part to several skip patterns in the enrollment survey that have inadvertently led to more adults receiving the mail mode offer before web participation options are fully explored. As a result, some adults who might be viable web participants are instead being routed to, and accepting, the mail mode offer before the web mode or tablet loan offer can be extended. This includes adults who report having some access to the Internet or email and who might be comfortable participating in the panel studies online.

Given FDA's preference to establish a primarily web-based panel in order to include multimedia images in the planned experimental and observational studies, we are also requesting approval for minor modifications to skip patterns, instructions, and programming checks in the enrollment survey to ensure that the web mode and tablet loan offers are being considered first, before the mail mode offer, for all eligible adults who may be capable web participants.

The panel recruitment protocol provides for the loan of a tablet computer to select eligible adults to facilitate their online participation in the panel studies. Since clearance was provided in June 2016, the tablet computer model that is available for purchase and loan to panel members has changed. The panel member Tablet Consent Form and Equipment Agreement and Receipt Form need to be updated to reflect the change in tablet models.

OMB has requested that the “DON’T KNOW” response option for the race and ethnicity items in the panel questionnaires be removed.

Table 1 provides a summary of the non-substantive changes that have been made to the Enrollment Survey (Attachments 1-3, 2-3). Tracked and clean versions of the English- and Spanish-language questionnaires that have been modified are provided below.

Table 2 provides a summary of the non-substantive changes that have been made to the Tablet Consent Form (Attachments 3-26, 4-26) and the Equipment Agreement and Receipt Form (Attachments 3-27, 4-27). Tracked and clean versions of the English- and Spanish-language materials that have been modified are provided.

Table 3 provides a summary of the changes made to the applicable items in the Field Screener and Enrollment Survey (Attachments 1.2, 1.3, 2.2, 2.3). Tracked and clean versions of the English- and Spanish-language materials that have been modified are provided.

Track change documents



Attachment_1_TrackAttachment_2_TrackAttachment_3_TrackAttachment_4_Track
ed.pdf ed.pdf ed.pdf ed.pdf

Table 1. Summary of Changes to Enrollment Questionnaires

Item Number	Page Number*	Change	Revised Text in Tracked Changes	Rationale	Prior Approval Given by OMB
ESB8	8 (8)	Edit	<p>ESB8. [IF <u>ESB1 = 1 OR ESB3 = 1 OR ESB5 = 1 OR ESB7 = 1</u>, FILL: <u>We expect most panel members will be able to participate in the short surveys online, that is via the web.</u> Based on the information you've provided, it appears you have convenient access to the Internet. This means you can complete the short surveys online through the secure TCS panel website.]</p> <p>[ELSE, FILL: Based on the information you've provided, it appears the best way for you to participate in the panel is by mail. This means we can mail you a paper questionnaire for each of the short surveys. Once you answer the questions, you can simply return the questionnaire to us in the postage-paid envelope we provide.]</p> <p>[ALL]: Is this a convenient way for you to participate in the panel?</p> <p>¹ <input type="checkbox"/> YES → GO TO ESB10</p> <p>² <input type="checkbox"/> NO → <u>IF ESB1 =1 OR ESB3 = 1 OR ESB5 = 1 OR ESB7 = 1, GO TO ESB9CHK. ELSE, GO TO ESB9CHK2. ELSE, CHECK BOX 4.</u></p>	<p>The fill logic for item ESB8 has been revised so that all eligible adults who report having internet in the home (ESB1 = 1), regular access to internet outside the home (ESB3 = 1), or a personal email address (ESB7 = 1) are first offered web participation. Currently, only those adults who report they can successfully access the internet whenever they want (ESB5 = 1) start with the web offer. This change will ensure that all adults who report some form of internet or email access are offered web mode first. The revised question stem explains that we expect most panel members can participate successfully online. The response option skip logic routes adults who declined the initial mail mode offer to the new tablet loan item.</p>	<p>Base item approved by OMB on 6/8/16</p>
ESB9CHK	8 (9)	Edit	<p>ESB9CHK: FI: ENCOURAGE WEB PARTICIPATION (E.G., 2-3 SHORT SURVEYS/YEAR, SECURE TCS WEBSITE, DATA ENCRYPTED WHEN SENT TO RTI, EASY TO LOGIN/COMPLETE SURVEYS ONLINE). ENTER "1" IF R SAYS WEB PARTICIPATION IS CONVENIENT. ELSE, ENTER "2" TO MOVE TO MAIL MODE OFFER.</p>	<p>The interviewer instructions at item ESB9CHK have been enhanced to encourage web-capable adults to participate online, emphasizing the ease of online participation and the security of the website and collected data. The reference to "MAIL MODE OFFER" has been removed as adults should be considered for tablet loan</p>	<p>Base item approved by OMB on 6/8/16</p>

Item Number	Page Number*	Change	Revised Text in Tracked Changes	Rationale	Prior Approval Given by OMB
			¹ <input type="checkbox"/> WEB MODE IS CONVENIENT FOR R → GO TO ESB10 ² <input type="checkbox"/> WEB MODE IS NOT CONVENIENT FOR R → GO TO <u>ESB9CHK2</u> <u>CHECK BOX 4</u>	before mail. This provides interviewers with additional instructions to encourage web participation, including ease of online participation and security of website and collected data.	
ESB9CHK2	8 (9)	New	<p><u>ESB9CHK2: Because our goal is to enroll as many people as possible to complete the panel surveys online, there may be another way you can take part. A small number of panel members may be eligible for the loan of a tablet computer while they are in the panel. The tablet loan may make it more convenient to complete the short panel surveys on the study website. Is this something you might be interested in?</u></p> <p>–</p> ¹ <input type="checkbox"/> YES, TABLET LOAN WOULD ENABLE R'S WEB PARTICIPATION → GO TO <u>ESBEXT2</u> ² <input type="checkbox"/> NO, TABLET LOAN IS NOT A VIABLE OPTION FOR R → GO TO CHECK BOX 4	A new scripted check, ESB9CHK2, has been added to assist interviewers in more smoothly transitioning to the potential tablet loan offer. This item will be presented to all adults who decline their initial mode offer (web or mail) to determine if the loan of a tablet would enable their online participation in the panel studies. If the answer is yes, the case will be reviewed by field management staff and a decision will be made about the device loan. This provides interviewers with scripted text to transition to potential tablet loan offer, while explaining the tablet would be on loan while participating in the panel. This ensures more adults are considered for a potential tablet loan offer, and thus online study participation.	NEW
CHECK BOX 4	8-9 (9)	Edit	<p>CHECK BOX 4: CONSIDER ALTERNATE MODE OFFER.</p> <p>IF <u>ESB9CHK2</u> = 2</p> <p>IF WEB OFFERED AT ESB8: IF <u>ESB1 = 1 OR ESB3 = 1 OR ESB5 = 1 OR ESB7 = 1</u>, → GO TO ESB9.</p> <p>IF MAIL OFFERED AT ESB8: IF <u>ESB1 NE 1 AND ESB3 NE 1 AND ESB5 NE 1 AND ESB7 NE 1</u> POTENTIAL TABLET: <u>ESB5 = 2, ESB3 = 1</u> → GO TO ESBEXT2.</p> <p>IF MAIL OFFERED, NO TABLET: <u>ESB5 = 2, ESB3 = 2</u> → GO TO EXBEXT2</p>	Ensures mail mode offer in ESB9 is limited to those adults who were offered both web and tablet loan but indicated they were not interested or able to participate online.	Base item approved by OMB on 6/8/16
ESBEXT2	9 (10)	Edit	<p>ESBEXT2: We would really like you to join the TCS panel. [IF <u>ESB9CHK2 = 1, FILL: I</u></p>	Created minor wording variations in exit script for adults being considered	Base item approved by

Item Number	Page Number*	Change	Revised Text in Tracked Changes	Rationale	Prior Approval Given by OMB
			<p><u>will talk to my supervisor to see if you may be eligible for the loan of a tablet computer while you are in the panel or if there is another way for you to participate. / ELSE, FILL: I will talk to my supervisor to see if there is another way for you to participate.] I will contact you again once I speak with him/her.</u></p> <p>What would be the best telephone number for me to contact you at?</p>	for tablet vs mail mode alternatives.	OMB on 6/8/16

*Page numbers in parentheses show the location of the changes in the corresponding Spanish questionnaire.

Table 2. Summary of Changes to Respondent Materials

Material	Attachment Number	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
Tablet Consent Form	3-26, 4-26			X	The reference to the “Samsung 3” tablet series has been revised to “Samsung” tablet in the “Procedures” and “Financial Considerations” sections of the consent form. This is the more accurate general reference for the loaner tablets since the original tablet series has changed.	Base item approved by OMB on 6/8/16
Equipment Agreement and Receipt Form	3-27, 4-27			X	The references to the Samsung Galaxy “Tab E” device have been updated to the “Tab A” model based on the device available for loan to panel members. This will specify the exact equipment components that are loaned to panel members during their time in the panel.	Base item approved by OMB on 6/8/16

Table 3. Summary of Changes to Panel Questionnaires

Questionnaire	Item Number	Page Number*	Change	Revised Text in Tracked Changes	Rationale	Prior Approval Given by OMB
Field Screener (Attachments 1.2, 2.2)	SCC12	7 (7)	Edit	<p>SCC12. (IF LOOP 1, FILL "Are you", ELSE FILL "Is [NAME]") Hispanic, [IF SCC6 =1 OR -2, FILL: Latino / IF SCC6 = 2, FILL: Latina], or of Spanish origin?</p> <p>1 <input type="checkbox"/> YES 2 <input type="checkbox"/> NO -1 <input type="checkbox"/> DON'T KNOW -2 <input type="checkbox"/> REFUSED</p>	"DON'T KNOW" option removed at request of OMB	Base item approved by OMB on 6/8/16
	SCC13	7 (8)	Edit	<p>SCC13. What is (IF LOOP 1, FILL "your", ELSE IF SCC6 = 1, FILL: his/IF SCC6 = 2, FILL her)/IF SCC6 = -2, FILL [NAME's] race? I'm going to read a list. Please select one or more.</p> <p>1 <input type="checkbox"/> White 2 <input type="checkbox"/> Black or African American 3 <input type="checkbox"/> American Indian or Alaska Native 4 <input type="checkbox"/> Asian 5 <input type="checkbox"/> Native Hawaiian or Other Pacific Islander -1 <input type="checkbox"/> DON'T KNOW -2 <input type="checkbox"/> REFUSED</p>	"DON'T KNOW" option removed at request of OMB	Base item approved by OMB on 6/8/16
Enrollment Survey** (Attachments 1.3, 2.3)	ESC9	14 (15)	Edit	<p>ESC9. Are you Hispanic, [IF ESC3 not blank, then IF ESC3 =1, FILL: Latino / IF ESC3 = 2, FILL: Latina else if primary then GENDER (Male=Latino/Female=Latina) from FIELD SCREENER (SCC6), if alternate then GENDER (Male=Latino/Female=Latina) from FIELD SCREENER (SCC6), or of Spanish origin?</p> <p>1 <input type="checkbox"/> YES 2 <input type="checkbox"/> NO -1 <input type="checkbox"/> DON'T KNOW -2 <input type="checkbox"/> REFUSED</p>	"DON'T KNOW" option removed at request of OMB	Base item approved by OMB on 6/8/16

Questionnaire	Item Number	Page Number*	Change	Revised Text in Tracked Changes	Rationale	Prior Approval Given by OMB
	ESC10	14 (15)	Edit	<p>ESC10. What is your race? I'm going to read a list. Please select one or more. (READ LIST. SELECT ALL THAT APPLY.)</p> <p>1 <input type="checkbox"/> White</p> <p>2 <input type="checkbox"/> Black or African American</p> <p>3 <input type="checkbox"/> American Indian or Alaska Native</p> <p>4 <input type="checkbox"/> Asian, or</p> <p>5 <input type="checkbox"/> Native Hawaiian or Other Pacific Islander?</p> <p>1 <input type="checkbox"/> DON'T KNOW</p> <p>2 <input type="checkbox"/> REFUSED</p>	"DON'T KNOW" option removed at request of OMB	Base item approved by OMB on 6/8/16

*Page numbers in parentheses show the location of the changes in the corresponding Spanish questionnaire.

**Tracked and clean versions of the English and Spanish Enrollment Survey include revisions currently undergoing OMB review per the March 20, 2017 change request.