

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

### Change Request (83-C)

January 22, 2021

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate several non-substantive changes to the questionnaires.

### Overview of the Change Request for OMB Control No. 0910-0815

Based on final review, programming, and testing of the questionnaires, several non-substantive changes are needed in advance of the initial implementation phase of the panel. No changes to other study materials are requested. Additionally, there is no change in the burden estimate included in the original clearance request. All changes described in this memorandum and reflected in the attachments have been approved by the Institutional Review Board at RTI International (RTI).

#### Questionnaire Changes

Questionnaire changes are focused on assuring the correct question wording and routing for each item, ensuring consistency across panel questionnaires, and improving alignment with the National Health Interview Survey (NHIS). In addition, several typographical errors and fonts have also been corrected in the questionnaire specifications. Minor changes in several questionnaire instructions are designed to improve the readability of mail survey responses during optical scanning and simplify administration of the item by an interviewer.



Att #	Type	Attachment Title	Tracked Versions
1	Revised	Questionnaire English	 questionnaires_1_final.pdf
2	Revised	Questionnaire Spanish	 questionnaires spanish clean.pdf

Table 1 provides a summary of the non-substantive changes that have been made to four panel questionnaires: Mail Screener (Attachments 1-1, 2-1), Field Screener (Attachments 1-2, 2-2), Enrollment Survey (Attachments 1-3, 2-3), and Baseline Survey (1-4, 2-4). This memo also includes tracked and clean versions of the English- and Spanish-language questionnaires that have been modified.

**Table 1. Summary of Changes to Panel Questionnaires**

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
Mail Screener (Attachments 1-1, 2-1)	“Start Here”	2			X	Inserted instruction to complete form using blue or black ink <u>RATIONALE</u> : Improve scanning performance.	Base item approved by OMB on 6/8/16
Field Screening Instrument (Attachments 1-2, 2-2)	SCD1	10			X	Inserted skip instruction for “no” response; underlined “cigarettes” for emphasis <u>RATIONALE</u> : Align with NHIS screening of cigarette users; ensure consistency with other items in screener.	Base item approved by OMB on 6/8/16
	SCD3	10 (11)			X	Inserted “regular” in on-screen banner and question text <u>RATIONALE</u> : Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
Enrollment Survey (Attachments 1-3, 2-3)	ESA3	16 (17)			X	Inserted skip instruction for “no” response; underlined “cigarettes” for emphasis <u>RATIONALE</u> : Align with NHIS screening of cigarette users; ensure consistency with other items in questionnaire.	Base item approved by OMB on 6/8/16
	ESA4	16 (17)			X	Underlined “cigarettes” for emphasis <u>RATIONALE</u> : Ensure consistency with other items in questionnaire.	Base item approved by OMB on 6/8/16
	ESB9	21 (23)			X	Revised wording of interviewer instruction; created separate interviewer instruction screen at ESB9CHK <u>RATIONALE</u> : Improve item administration for interviewers.	Base item approved by OMB on 6/8/16
	CHECK BOX 4	21 (23)			X	Updated skip logic <u>RATIONALE</u> : Update programming instructions to improve exit script transition for potential tablet candidates	Base item approved by OMB on 6/8/16
Baseline Survey (Attachments 1-4, 2-4)	PBB1	39 (43)			X	Moved location of “a day” to end of question <u>RATIONALE</u> : Align with wording of other items in baseline questionnaire and NHIS.	Base item approved by OMB on 6/8/16
	PBB2	40 (43)			X	Removed date fill text, “that is, since [FILL DATE]” <u>RATIONALE</u> : Align with NHIS.	Base item approved by OMB on 6/8/16
	PBB3	40 (43)			X	Inserted “the” and moved location and underlined “cigarettes” in question text <u>RATIONALE</u> : Align with parallel items on cigar and smokeless tobacco in baseline questionnaire.	Base item approved by OMB on 6/8/16
	PBB7	42 (45)			X	Added “regular” to question wording and on-screen banner <u>RATIONALE</u> : Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
	PBB8	42 (45)			X	Inserted "the" and moved location of "a day" to end of question; also added "regular" to question wording <u>RATIONALE:</u> Align with wording of other items in baseline questionnaire and NHIS, and for consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
	PBB9	43 (45)			X	Added "regular" to question wording; also removed date fill text, "that is, since [FILL DATE]" <u>RATIONALE:</u> Align with NHIS, and for consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
	PBB10	43 (46)			X	Added "the" and "regular" to question wording <u>RATIONALE:</u> Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
	PBB10a	43 (46)			X	Added "regular" to question wording <u>RATIONALE:</u> Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
	PBB11	43 (46)			X	Added "regular" to question wording; also included "cigarillos, or little filtered cigars" in question text <u>RATIONALE:</u> Consistency with cigar introduction, screener, and enrollment questionnaires, and wording of other cigar items in baseline questionnaire.	Base item approved by OMB on 6/8/16
	CHECK BOX 5	44 (47)			X	Updated skip pattern <u>RATIONALE:</u> Ensure proper routing for new item PBB12a	Base item approved by OMB on 6/8/16
	PBB12a	44 (47)	X			Inserted new item on number of times panel member now uses smokeless tobacco a day <u>RATIONALE:</u> Consistency with parallel intensity question for cigarettes and cigars.	Item not previously approved
	PBB13	44 (47)			X	Removed date fill text, "that is, since [FILL DATE]" <u>RATIONALE:</u> Align with NHIS.	Base item approved by OMB on 6/8/16
	PBB14	45 (47)			X	Inserted "the" and changed item from a categorical to open-ended response; also revised skip patterns to ensure item only asked of "some days" smokeless users <u>RATIONALE:</u> Consistency with parallel cigarette and cigar items.	Base item approved by OMB on 6/8/16
	PBB17	46 (48)		X		Deleted item on number of containers of smokeless tobacco used per week; replaced with PBB12a (number of times panel member now uses smokeless tobacco a day) <u>RATIONALE:</u> Consistency with parallel intensity question for cigarettes and cigars.	Base item approved by OMB on 6/8/16
	PBB20I2	47			X	Changed "some day" to "some days" in question text	Base item approved

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
						RATIONALE: Correct typographical error in English questionnaire.	by OMB on 6/8/16
	PBB2013	47 (50)			X	Removed date fill text, "that is, since [FILL DATE]"; also updated question wording to "did you use e-cigarettes" RATIONALE: Align with NHIS; correct typographical error.	Base item approved by OMB on 6/8/16
	PBB21	47 (50)			X	Added "regular" to question wording RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16
	PBB22	48 (50)			X	Added "regular" to question wording RATIONALE: Consistency with cigar introduction, screener, and enrollment questionnaires.	Base item approved by OMB on 6/8/16

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