

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

Change Request (83-C)

December 28, 2016

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate several non-substantive changes to the questionnaires and respondent materials for establishing the panel based on findings and lessons learned from the initial implementation phase.

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

Between August 18 and October 16, 2016, an initial implementation phase of the National Panel of Tobacco Consumer Studies (TCS) was conducted to test screening and recruitment protocols, field procedures, and respondent materials in advance of the national implementation effort.

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 were approved by the Institutional Review Board at RTI International (RTI) on November 29, 2016.

Questionnaire Changes

Based on field observations and experiences during the initial implementation phase, minor revisions are requested to the mail screener, field screener, enrollment survey, and baseline survey. These changes include:

- Addition of FDA logo to the mail screener to be consistent with already approved materials
- Update to the survey return address on the mail screener
- Minor edits to introductory and exit script text for improved readability or consistency across panel materials
- Removal of redundant or unnecessary text or instructions, or corrections to instructions
- Addition of “Don’t Know” and “Refused” options for all demographic questions
- Reordering of several questions to improve survey flow
- Refinements to Spanish translations for several questions
- Refinements to programming specifications
- Removal of questions not needed for analysis or screening

Respondent Material Changes

Minor revisions are also requested to the respondent materials based on interviewer feedback:

- Reformatted and streamlined the doorstep transition script for improved readability by interviewers
- Added references to “Adult” residents to lead letters and CAPI nonresponse letters; minor cosmetic changes made to the letters to improve readability and emphasize important points in the text to encourage participation
- Added FDA logo to select respondent materials to be consistent with already approved materials

- Resolved minor inconsistencies in descriptions of the panel participation requirements across materials

During the initial implementation phase, a number of households refused to begin the screening process at the doorstep, assuming instead that no one in the household was eligible for the panel. Conversion attempts with these and other pending screening and enrollment households are critical to achieving the 4,000-member enrollment target within the allotted schedule and budget. Additional, targeted materials to address specific nonresponse situations are needed. These include:

- Refusal letters for partial enrollment situations and early doorstep refusals before screening is initiated
- A screener reminder postcard announcing the interviewer’s upcoming visit
- Priority letters for pending screening and enrollment cases that inform respondents that the field period is ending soon and their participation is important
- A controlled access letter for building/property managers to inform them of the interviewer’s visit and request their assistance in providing access to gated communities or controlled-access buildings

Track change documents



ATTACHMENT_1_TR ACKED.pdf ATTACHMENT_2_TR ACKED.pdf ATTACHMENT_3_TR ACKED.pdf ATTACHMENT_4_TR ACKED.pdf

Table 1 provides a summary of the non-substantive changes that have been made to the 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). Table 2 lists the changes that have been made to respondent materials (Attachments 3 and 4). Tracked and clean versions of the English- and Spanish-language questionnaires and respondent materials that have been modified are provided.

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 Screening Instrument (Attachment 1-1, 2-1)	Logo / Thank You Box	2 (2)			X	Added FDA logo; updated RTI return address <u>RATIONALE:</u> Consistency with other materials; update address for national survey returns	Base item approved by OMB on 6/8/16
Field Screening Instrument (Attachments 1-2, 2-2)	SCBINTRO	3 (3)			X	Edited sentence referring to lead letter <u>RATIONALE:</u> Make it active voice and not imply what respondent should have done/received	Base item approved by OMB on 6/8/16
	SCBCONSENT	(4)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	SCC1	(5-6)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	SCC6	7 (8)			X	Added "Refused" response option <u>RATIONALE:</u> Provide answer choice if screening respondent will not give gender of household members	Base item approved by OMB on 6/8/16
	SCC8, SCC9, SCC10, SCC11, SCC12, SCC14	8-10 (8-10)			X	Added "Don't Know" and "Refused" response options; updated fill logic when gender is missing; refined Spanish translation <u>RATIONALE:</u> Provide answer choice and updated fill logic if screening respondent will not give active duty status, marital status, education, employment, Hispanic origin, or time spent in home for household members. Improve alignment with English text	Base item approved by OMB on 6/8/16
	SCC13	9 (9-10)			X	Added "Don't Know" and "Refused" response options; updated fill logic when gender is missing <u>RATIONALE:</u> Provide answer choice and updated fill logic if screening respondent will not give race of household members	Base item approved by OMB on 6/8/16
	SCDINTRO	10 (10)			X	Added fill text instruction <u>RATIONALE:</u> Provide fill when gender is missing	Base item approved by OMB on 6/8/16
	SCD2	(11)			X	Corrected Spanish response option 3 <u>RATIONALE:</u> Corrected typo	Base item approved by OMB on 6/8/16
	SCD4	(11-12)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	SCE1, SCE6	11-12 (12-13)			X	Updated section header; added "Don't Know" and "Refused" response options <u>RATIONALE:</u> Provide answer choice if screening respondent will not provide count of children	Base item approved by OMB on 6/8/16
SCE3, SCE4,	12		X		Deleted questions	Base item approved	

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
	SCE5, CHECK BOX 9	(12-13)				<u>RATIONALE</u> : Not needed for analysis	by OMB on 6/8/16
	CHECK BOX 10	13 (13)			X	Added instructions to handle "Don't Know" and "Refused" responses <u>RATIONALE</u> : Update sample selection parameters	Base item approved by OMB on 6/8/16
	SCEEXIT4	14 (14)			X	Revised exit script wording for ineligible households <u>RATIONALE</u> : Eliminate fill text and simplify scripting given household members may be ineligible for multiple reasons	Base item approved by OMB on 6/8/16
	CHECK BOX 11	15 (15)			X	Changed instruction to reference "Enrollment" vs "Baseline" survey <u>RATIONALE</u> : Correct programming instruction	Base item approved by OMB on 6/8/16
Enrollment Survey (Attachments 1-3, 2-3)	ESINTRO	(17)			X	Refined Spanish translation <u>RATIONALE</u> : Improve alignment with English text	Base item approved by OMB on 6/8/16
	ESA1	17 (18)			X	Reworded question, eliminated "if not obvious"; added "Don't Know" and "Refused" response options. Refined Spanish translation. <u>RATIONALE</u> : Item needed for eligibility verification before enrollment begins; provide answer choice if sampled adult will not respond, consistent with field screener. Improve alignment with English text	Base item approved by OMB on 6/8/16
	ESA2	17 (18)			X	Added "Don't Know" and "Refused" response options <u>RATIONALE</u> : Provide answer choice if sampled adult will not respond, consistent with field screener	Base item approved by OMB on 6/8/16
	ESA2a	17 (18-19)			X	Moved item from ESC series to ESA eligibility verification section <u>RATIONALE</u> : Item needed for eligibility verification before enrollment begins	Base item approved by OMB on 6/8/16
	ESA5, ESA6	(19-20)			X	Refined Spanish translation <u>RATIONALE</u> : Improve alignment with English text; correct translation for smokeless product response option	Base item approved by OMB on 6/8/16
	CHECK BOX 3	19 (20)			X	Edited programming instructions; added reference to new disposition codes as needed <u>RATIONALE</u> : Accommodate "Don't Know" and "Refused" and active duty military responses	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
	ESAEXT1, ESAEXT2, ESAEXT3, ESAEXT4, ESAALT1, ESAALT2, ESAALT3	19-21 (21-22)			X	Updated wording of exit scripts; added reference to new disposition codes as needed. Refined Spanish translation. <u>RATIONALE:</u> Update scripting and codes to match eligibility verification items in ESA1-3; improve alignment with English text as needed	Base item approved by OMB on 6/8/16
	ESBINTRO	(22)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	ESB8INTRO	23 (24)			X	Updated reference to number of surveys per year <u>RATIONALE:</u> Consistency with other materials	Base item approved by OMB on 6/8/16
	CHECK BOX 4, ESB9	23-24 (25)			X	Updated routing and programming instructions <u>RATIONALE:</u> Correct routing to exit script; delete unnecessary logic	Base item approved by OMB on 6/8/16
	CHECK BOX 4A	(26)			X	Deleted check box from Spanish instrument <u>RATIONALE:</u> Align English and Spanish survey specifications	Base item approved by OMB on 6/8/16
	ESBEXT1	24 (26)		X		Deleted exit script <u>RATIONALE:</u> Not needed per CHECK BOX 4 edit	Base item approved by OMB on 6/8/16
	ESBEXT2A	24 (26)			X	Reworded response option 2 <u>RATIONALE:</u> Better identify when sampled adult finds web mode inconvenient	Base item approved by OMB on 6/8/16
	ESB12	(28)			X	Removed reference to equipment agreement in Spanish version <u>RATIONALE:</u> Align English and Spanish survey specifications	Base item approved by OMB on 6/8/16
	ESC1	27 (28-29)			X	Added "Don't Know" and "Refused" response options <u>RATIONALE:</u> Consistency with other items collecting panel demographics/characteristics	Base item approved by OMB on 6/8/16
	ESC2	27 (29)			X	Removed reference to active duty military and full-time/part-time household status <u>RATIONALE:</u> Items moved to ESA series for eligibility verification	Base item approved by OMB on 6/8/16
	ESC4	28 (30)			X	Removed programming instructions <u>RATIONALE:</u> Not needed	Base item approved by OMB on 6/8/16
	ESC4A	28 (30)			X	Deleted fill text <u>RATIONALE:</u> Not needed for enrollment scripting	Base item approved by OMB on 6/8/16
	ESC5	28 (30)			X	Moved item to eligibility verification section (now	Base item approved

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
						item ESA2a) <u>RATIONALE:</u> Item needed for eligibility verification before enrollment begins	by OMB on 6/8/16
	ESC6, ESC7, ESC8, ESC9, ESC10	29-30 (30-32)			X	Added "Don't Know" and "Refused" response options <u>RATIONALE:</u> Consistency with comparable field screening questions	Base item approved by OMB on 6/8/16
	ESC11	30 (32)		X		Removed item <u>RATIONALE:</u> Status in household is collected in item ESA1 in eligibility verification section	Base item approved by OMB on 6/8/16
	ESC14	31 (32)	X			Added new question to collect panel member birth month and year <u>RATIONALE:</u> Track panel member age in future experimental and observational studies	NEW
	ESD1	(33)			X	Update interviewer instruction <u>RATIONALE:</u> Align English and Spanish survey specifications	Base item approved by OMB on 6/8/16
	ESD7	(35)			X	Corrected routing instruction <u>RATIONALE:</u> Align English and Spanish survey specifications	Base item approved by OMB on 6/8/16
	ESDEND	(40)	X			Added item <u>RATIONALE:</u> Align English and Spanish survey specifications	NEW (Spanish)
Baseline Survey (Attachments 1-4, 2-4)	PBINTIT1A	(41)		X		Deleted part of programming instruction <u>RATIONALE:</u> Align English and Spanish survey specifications	Base item approved by OMB on 6/8/16
	PBA1, PBA2, PBA3	(42-43)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	PBB2	(45-46)			X	Corrected numeric range in Spanish version <u>RATIONALE:</u> Align with English version	Base item approved by OMB on 6/8/16
	PBB9	46 (49)			X	Corrected skip in programmer note; updated scripted range probe <u>RATIONALE:</u> Align with response field range; align English and Spanish versions	Base item approved by OMB on 6/8/16
	PBB10A	(50)			X	Added programmer note in Spanish version <u>RATIONALE:</u> Align with English version	Base item approved by OMB on 6/8/16
	PBC1	(54)			X	Refined Spanish translation <u>RATIONALE:</u> Improve alignment with English text	Base item approved by OMB on 6/8/16
	PBC5	52-53			X	Deleted detailed item on types of Apps used	Base item approved

Questionnaire	Item Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
		(56)				RATIONALE: Item not needed for analysis or tech support purposes; item PBC4 meets this need	by OMB on 6/8/16

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

Table 2. Summary of Changes to Respondent Materials

Material	Attachment Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
Screener Lead Letter	3-2, 4-2	2 (2)			X	Added "Adult" to greeting; used bolding in paragraph on what participation involves <u>RATIONALE</u> : Clarify who the letter is directed to; emphasize important text about survey panel	Item approved by OMB on 6/8/16
Brochure	3-3, 4-3	3-4 (3-4)			X	Revised number of surveys in description of panel participation requirements <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Screener Nonresponse / Unable to Contact Letters	3-4, 3-5, 3-6, 3-7, 3-8, 3-9, 3-10, 4-4, 4-5, 4-6, 4-7, 4-8, 4-9, 4-10	5-11 (5-11)			X	Added "Adult" or NAME fill to greeting; used bolding in paragraph on what participation involves <u>RATIONALE</u> : Clarify who the letter is directed to; emphasize important text about survey panel	Item approved by OMB on 6/8/16
CAPI Non-Response Letters	3-11, 3-12, 3-13, 3-14, 3-15, 3-16, 3-17, 3-18, 3-19, 3-20, 4-11, 4-12, 4-13, 4-14, 4-15, 4-16, 4-17, 4-18, 4-19, 4-20	12-21 (12-21)			X	Added "Adult" to greeting; used bolding in paragraph on what participation involves <u>RATIONALE</u> : Clarify who the letter is directed to; emphasize important text about survey panel	Item approved by OMB on 6/8/16
Mail/Web Topical Survey Nonresponse Letter	3-22, 3-24, 4-22, 4-24	22-23 (22-23)			X	Added FDA logo alongside TCS logo <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Web/Mail/Tablet Consent Forms	3-25, 3-26, 4-25, 4-26	24-25 (24-27)			X	Revised reference to number of surveys per year <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Tablet Equipment Agreement	3-27, 4-27	26 (28-29)			X	Updated tablet model <u>RATIONALE</u> : Match model specifications of final tablet selection	Item approved by OMB on 6/8/16
Doorstep Transition Script	3-30, 4-30	27-29 (30-32)			X	Simplified wording and updated reference to number of surveys per year; split into screening, enrollment, and device options sections <u>RATIONALE</u> : Reduce verbiage, improve formatting for improved interviewer readability; consistency with other materials	Item approved by OMB on 6/8/16
Incentive Thank You Letter	3-32, 4-32	30 (33)			X	Added FDA logo alongside TCS logo <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Mail Reminder Postcard	3-35, 4-35	31 (34)			X	Added FDA logo alongside TCS logo <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Topical Mail/Web	3-38, 3-39,	32-33			X	Added FDA logo alongside TCS logo	Item approved by

Material	Attachment Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
Reminder Postcard	4-38, 4-39	(35-36)				<u>RATIONALE</u> : Consistency with other materials	OMB on 6/8/16
TCS Panel Member Alert Non-Response Scripts	3-41, 4-41	34-42 (37-43)			X	<ul style="list-style-type: none"> Added "Heads-Up" Announcements scripts by contact mode Reduced characters in post-enrollment automated Text messages Added reminder about frequency of survey requests and additional methods for contacting RTI or updating contact information <u>RATIONALE</u> : Announce upcoming topical study request to confirm contact information; reduce length of text messages to meet SMS messaging requirements across multiple carriers; remind panelists of expected survey frequency and all means of maintaining contact with RTI	Item approved by OMB on 6/8/16
Website Screens	3-43, 4-43	51 (50-51)			X	Updated reference to number of surveys per year <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Disenrollment Letters	3-44, 3-45, 4-44, 4-45	56-57 (56-57)			X	Added FDA logo alongside TCS logo <u>RATIONALE</u> : Consistency with other materials	Item approved by OMB on 6/8/16
Screener Nonresponse Priority Letter	3-46, 4-46	58 (58)	X			Added letter to prompt screening participation before field period ends <u>RATIONALE</u> : Encourage participation in field screening before end of data collection period	NEW
CAPI Nonresponse Priority Letter	3-47, 4-47	59 (59)	X			Added letter to prompt enrollment survey participation before field period ends <u>RATIONALE</u> : Encourage eligible sampled adult's enrollment before end of data collection	NEW
Screener Nonresponse Postcard	3-48, 4-48	60 (60)	X			Added postcard to announce upcoming interviewer visit <u>RATIONALE</u> : Encourage participation in field screening when interviewer visits household	NEW
Screener Nonresponse Letter – Eligibility Determination Needed	3-49, 4-49	61 (61)	X			Added letter to convert early doorstep refusals <u>RATIONALE</u> : Encourage household to answer screening questions to determine panel eligibility	NEW
CAPI Nonresponse Partial Enrollment Follow-up Letter	3-50, 4-50	62 (62)	X			Added letter to respond to partial enrollments (enrollment process begun but not completed) <u>RATIONALE</u> : Encourage sampled adult to complete remainder of enrollment process	NEW
Controlled Access Letter	3-51	63	X			Added letter to property managers in controlled access/gated community situations (English only) <u>RATIONALE</u> : Inform property management of	NEW

Material	Attachment Number	Page Number*	Addition	Deletion	Edit	Change and Rationale	Prior Approval Given by OMB
						interviewer's visit to property and request access; sampled address/unit not identified in letter	

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