**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



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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Improve alignment with English text | Base item approved by OMB on 6/8/16 |
| SCC1 | (5-6) |  |  | X | Refined Spanish translation  RATIONALE: Improve alignment with English text | Base item approved by OMB on 6/8/16 |
| SCC6 | 7 (8) |  |  | X | Added “Refused” response option  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Provide fill when gender is missing | Base item approved by OMB on 6/8/16 |
| SCD2 | (11) |  |  | X | Corrected Spanish response option 3  RATIONALE: Corrected typo | Base item approved by OMB on 6/8/16 |
| SCD4 | (11-12) |  |  | X | Refined Spanish translation  RATIONALE: 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  RATIONALE: Provide answer choice if screening respondent will not provide count of children | Base item approved by OMB on 6/8/16 |
| SCE3, SCE4, SCE5, CHECK BOX 9 | 12  (12-13) |  | X |  | Deleted questions  RATIONALE: Not needed for analysis | Base item approved by OMB on 6/8/16 |
| CHECK BOX 10 | 13 (13) |  |  | X | Added instructions to handle “Don’t Know” and “Refused” responses  RATIONALE: Update sample selection parameters | Base item approved by OMB on 6/8/16 |
| SCEXIT4 | 14 (14) |  |  | X | Revised exit script wording for ineligible households  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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.  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Accommodate “Don’t Know” and “Refused” and active duty military responses | Base item approved by OMB on 6/8/16 |
| 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.  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Align English and Spanish survey specifications | Base item approved by OMB on 6/8/16 |
| ESBEXT1 | 24 (26) |  | X |  | Deleted exit script  RATIONALE: Not needed per CHECK BOX 4 edit | Base item approved by OMB on 6/8/16 |
| ESBEXT2A | 24 (26) |  |  | X | Reworded response option 2  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Items moved to ESA series for eligibility verification | Base item approved by OMB on 6/8/16 |
| ESC4 | 28 (30) |  |  | X | Removed programming instructions  RATIONALE: Not needed | Base item approved by OMB on 6/8/16 |
| ESC4A | 28 (30) |  |  | X | Deleted fill text  RATIONALE: 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 item ESA2a)  RATIONALE: Item needed for eligibility verification before enrollment begins | Base item approved by OMB on 6/8/16 |
| ESC6, ESC7, ESC8, ESC9, ESC10 | 29-30 (30-32) |  |  | X | Added “Don’t Know” and “Refused” response options  RATIONALE: Consistency with comparable field screening questions | Base item approved by OMB on 6/8/16 |
| ESC11 | 30 (32) |  | X |  | Removed item  RATIONALE: 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  RATIONALE: Track panel member age in future experimental and observational studies | NEW |
| ESD1 | (33) |  |  | X | Update interviewer instruction  RATIONALE: Align English and Spanish survey specifications | Base item approved by OMB on 6/8/16 |
| ESD7 | (35) |  |  | X | Corrected routing instruction  RATIONALE: Align English and Spanish survey specifications | Base item approved by OMB on 6/8/16 |
| ESDEND | (40) | X |  |  | Added item  RATIONALE: Align English and Spanish survey specifications | NEW (Spanish) |
| Baseline Survey (Attachments 1-4, 2-4) | PBINTIT1A | (41) |  | X |  | Deleted part of programming instruction  RATIONALE: Align English and Spanish survey specifications | Base item approved by OMB on 6/8/16 |
| PBA1, PBA2, PBA3 | (42-43) |  |  | X | Refined Spanish translation  RATIONALE: Improve alignment with English text | Base item approved by OMB on 6/8/16 |
| PBB2 | (45-46) |  |  | X | Corrected numeric range in Spanish version  RATIONALE: 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  RATIONALE: 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  RATIONALE: Align with English version | Base item approved by OMB on 6/8/16 |
| PBC1 | (54) |  |  | X | Refined Spanish translation  RATIONALE: Improve alignment with English text | Base item approved by OMB on 6/8/16 |
| PBC5 | 52-53 (56) |  | X |  | Deleted detailed item on types of Apps used  RATIONALE: Item not needed for analysis or tech support purposes; item PBC4 meets this need | Base item approved 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: Consistency with other materials | Item approved by OMB on 6/8/16 |
| Topical Mail/Web Reminder Postcard | 3-38, 3-39,  4-38, 4-39 | 32-33 (35-36) |  |  | X | Added FDA logo alongside TCS logo  RATIONALE: Consistency with other materials | Item approved by OMB on 6/8/16 |
| TCS Panel Member Alert Non-Response Scripts | 3-41, 4-41 | 34-42 (37-43) |  |  | X | * 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   RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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  RATIONALE: 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)  RATIONALE: 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)  RATIONALE: Inform property management of interviewer’s visit to property and request access; sampled address/unit not identified in letter | NEW |

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