

**Measuring Consumer Comprehension of Displays of Harmful and
Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke
(OMB Control Number 0910-0880)**

Change Request

March 16, 2020

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to incorporate several non-substantive changes to the collection. These changes are proposed to enhance participant privacy and clarify our procedures.

Overview of the Change Request

Please note that there have been **no** changes to:

- The purpose and justification of data collection
- The mode of data collection
- The study design
- The outcomes assessed
- The approximate value of the compensation received by participants
- The voluntary nature of participation

Changes made to individual documents are described below.

Supporting Statement Part A



Updated_Supportin
g Statement_Part A_

- Clarified that Lightspeed (the company that hosts the online survey) partners with other survey companies for recruitment. Partners do not program the survey, collect data, or have access to data. Updated description of data security systems and processes.
- Updated the legal age for tobacco use from 18 to 21.
- Updated burden estimates and associated costs to reflect that more respondents may need to be screened in order to reach the desired sample size and that it may not be possible to close recruitment the exact moment that the total 4,500 completes are obtained.
- Updated the Project Schedule to match contract.

Supporting Statement Part B



Updated_Supportin
g Statement_Part B_

- Same clarification regarding Lightspeed's use of recruitment partners as

described in Part A above.

- Updated the number of survey items.
- Deleted contact information for an employee who no longer works on this project.

Appendix G: Online Survey Adult Consent



Appendix G HPHC2
Online Survey Adult

- Clarified information regarding data privacy and management, potential future use of deidentified data (per the revised Common Rule), and the requirements to receive an incentive.
- Updated Certificate of Confidentiality language to be more accurate and more easily understood.

Appendix H: Online Survey Parental Permission



Appendix H HPHC2
Online Survey Paren

- Clarified information regarding data privacy and management, potential future use of deidentified data (per the revised Common Rule), and the requirements to receive an incentive.
- Updated Certificate of Confidentiality language to be more accurate and more easily understood.

Appendix I: Online Survey Youth Assent



Appendix I HPHC2
Online Survey Youth

- To ensuring an appropriate readability level, removed unnecessary information and used a template for youth assent provided by RTI's IRB to guide edits to the required information.

Appendix J: Online Survey Screening Questions



Appendix J HPHC2
Online Survey Scree

- Clarified programming language.
- Updated age criteria for questions S5-S7 such that the questions are asked of participants younger than 21, to better align with the recent national Tobacco 21 policy.
- Removed "I do not wish to answer" from questions that are required to determine eligibility or fulfillment of quotas.
- Changed response options to items about ethnicity (G4) and race (G5) to match OMB guidelines.
- Added a question about past survey participation.

Appendix K: Online Survey Questionnaire



Appendix K HPHC2
Online Survey Quest

- Clarified programming language.
- Added debrief at the end of the survey to notify participants that the brand of cigarettes described in the study is a fictitious brand.
- Updated the URL for the website with information on how to quit using tobacco to smokefree.gov.

Appendix N: Online Adult Invitation Email



Appendix N HPHC2
Online Survey Adult

- Updated compensation language and names of mailboxes to make it generalizable to participants recruited through survey panels other than Lightspeed.

Appendix O: Online Parent/Youth Invitation Email



Appendix O HPHC2
Online Survey Paren

- Updated compensation language and names of mailboxes to make it generalizable to participants recruited through survey panels other than Lightspeed.

Editorial Changes Throughout Attachments

- Updated references of RIHSC to FDA IRB.
- Added OMB approval number and expiration date.
- Updated header and used brackets to clarify which information will not be shown to participants.
- Clarified incentive language as “account” rather than “Global Test Market account” (a term no longer used by the online survey vendor).
- For consent/assent/parental permission forms, updated consent/assent question to reflect that participants are consenting to both the screener and survey and noted that participants can print or take a screenshot of the consent form if he or she wants a copy.

New Documents Submitted

- Appendix P: Online Survey Parent/Youth Invitation Reminder Email



Appendix P HPHC2
Online Survey Paren

- Appendix Q: Online Survey Adult Invitation Reminder Email



Appendix Q HPHQ2
Online Survey Adult