UNITED STATES FOOD & DRUG ADMINISTRATION

**Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use**

**OMB Control Number 0910-0796**

**Change Request**

**July 9, 2020**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to update the research delivery mode. Due to the coronavirus (COVID-19) pandemic, Tobacco 21 regulations and the resulting impact to contractor capacity for on-site research operations, FDA seeks OMB concurrence of a non-substantive change to expand our options for data collection and respondent incentives.

We plan to modify our research protocol to reflect the inclusion of young adults, virtual/online focus groups and the use of individual interviews. The original approval outlined in-person focus groups for youth aged 12-17. The change would allow for the provision of conducting research online and in-person during study data collection among an extended age group. This change in protocol will allow for flexibility to conduct research online and in-person, age group expansion for comparison purposes and additional incentive options for online and young adult participation. There is no change to the burden hours.

**Overview of the Change Request**

* The age of respondents will be extended to 25. After much thought, we realized that accounting for Tobacco 21 regulations requires talking to older young adults as a comparison. Expanding the young adult age group from 18-21 to 18-25 will allow us to compare 18-21 year-olds to both youth participants as well as older young adults.
* Minimum participant numbers for groups will be reduced to accommodate differences in our ability to recruit for online research.
* For online research, youth participants will receive a $25 token of appreciation for participating; the parent/guardian of the youth will not receive a token of appreciation. There is no change to the youth participant or parent/guardian of the youth incentive amount for in-person research.
* Young adult participants aged 18-25 will receive an incentive of $50 for online participation and $75 for in-person participation as a token of appreciation.

Tracked and clean versions of the *OMB Approval Memo*, *Parental Permission Form (Appendix A)*, *Youth Assent Form (Appendix B)* and *Young Adult Consent Form (Appendix B1)* are provided as attachments in the below tables.

*Change Documentation*

|  |  |  |
| --- | --- | --- |
| **Instrument File** | **Document Type** | **Change** |
|  | OMB Approval Memo | * Revised text to include young adults (aged 18-25), individual interviews and virtual focus groups. * Updated text for inclusion of socio-cultural determinates of tobacco use discussion. * Revised number of focus groups. * Updated Section 6. Confidentiality of respondents. * Updated Section 7. Amount and justification for any proposed incentive   + Online/in-person research   + Young adult participants * Updated burden table “Type of Activity” to include young adults and interviews. |
|  | Appendix A – Parental Permission Form | * Revised/expanded text to reflect in-person and virtual research. * Updated text for inclusion of individual interviews. * Revised number of focus groups. * Added $25 youth incentive amount for online research participation. |
|  | Appendix B - Youth Assent Form | * Revised/expanded text to reflect in-person and virtual research. * Updated text for inclusion of individual interviews. * Revised number of focus groups. * Added $25 youth incentive amount for online research participation. |
|  | Appendix B1 – Young Adult Consent Form | * New form * Modified from *Youth Assent Form* to address expanded age group (young adults aged 18-25) * Modified incentive amounts to reflect $50 for online participation and $75 for in-person participation. |

*Clean Documents*

|  |  |
| --- | --- |
| **Instrument File** | **Document Type** |
|  | OMB Approval Memo |
|  | Appendix A – Parental Permission Form |
|  | Appendix B - Youth Assent Form |
|  | Appendix B1 – Young Adult Consent Form |