

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
 <p>OMB Approval Memo for CC Testing</p>	OMB Approval Memo	<ul style="list-style-type: none"> <li>Revised text to include young adults (aged 18-25), individual interviews and virtual focus groups.</li> <li>Updated text for inclusion of socio-cultural determinates of tobacco use discussion.</li> <li>Revised number of focus groups.</li> <li>Updated Section 6. Confidentiality of respondents.</li> <li>Updated Section 7. Amount and justification for any proposed incentive               <ul style="list-style-type: none"> <li>Online/in-person research</li> <li>Young adult participants</li> </ul> </li> <li>Updated burden table "Type of Activity" to include young adults and interviews.</li> <li>Revised/expanded text to reflect in-person and virtual research.</li> </ul>
 <p>Appendix A - Parental Form TC</p>	Appendix A - Parental Permission Form	<ul style="list-style-type: none"> <li>Updated text for inclusion of individual interviews.</li> <li>Revised number of focus groups.</li> <li>Added \$25 youth incentive amount for online research participation.</li> </ul>
 <p>Appendix B - Youth Assent Form TC</p>	Appendix B - Youth Assent Form	<ul style="list-style-type: none"> <li>Revised/expanded text to reflect in-person and virtual research.</li> <li>Updated text for inclusion of individual interviews.</li> <li>Revised number of focus groups.</li> <li>Added \$25 youth incentive amount for online research participation.</li> </ul>
 <p>Appendix B1 - Young Adult Consent TC</p>	Appendix B1 - Young Adult Consent Form	<ul style="list-style-type: none"> <li>New form</li> <li>Modified from <i>Youth Assent Form</i> to address expanded age group (young adults aged 18-25)</li> <li>Modified incentive amounts to reflect \$50 for online participation and \$75 for in-person</li> </ul>

participation.

*Clean Documents*

Instrument File	Document Type
 OMB Approval Memo for Creative Co	OMB Approval Memo
 Appendix A - Parental Form	Appendix A - Parental Permission Form
 Appendix B - Youth Assent Form	Appendix B - Youth Assent Form
 Appendix B1 - Young Adult Consent Form	Appendix B1 - Young Adult Consent Form