

**U.S. Food and Drug Administration
Center for Tobacco Products
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and
Communications
OMB Control Number 0910-0796
“Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco
Product Use”**

Change Request October 2022

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to account for the misuse of a previously approved individual generic request under control number (0910-0796). The individual Gen IC titled “Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use” utilized by the Office of Health Communication and Education (OHCE) in the Center for Tobacco Products (CTP) operated inconsistently within the spirit and guidance covering generic clearances. The individual Gen IC was approved (hereafter, referred to as the “approved Gen IC”) to enable OHCE to pursue a qualitative data collection to assess consumer reactions to draft strategic and creative concepts designed for public health education efforts for tobacco products. Subsequently, OHCE CTP conducted four studies that relied on similar methodology and study approaches as found in the approved Gen IC. As such, instead of utilizing the burden from the approved Gen IC, OHCE CTP should have sought OMB review and approval of the four qualitative studies (hereafter, referred to as the “four unapproved studies”). Collectively, the four unapproved studies used 1,638 hours (Study 1: 596 hours, Study 2: 281 hours, Study 3: 453 hours, Study 4: 308 hours) out of 3,511 stated in the approved Gen IC.

This memo summarizes the four studies that were inappropriately conducted under the approved Gen IC. While we are not submitting these collections for approval or review as part of new Gen ICs, we are submitting updated materials to ensure that the administrative record is clear as to what occurred and ensure that the appropriate burden hours are accounted for.

Overview of the Original Collection in the Approved Gen IC

The Gen IC ([“Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use”](#)), was approved in July of 2020 with approval through July of 2022. The collection was approved for 250 focus groups/interviews, held in-person or virtually, with 1,620 youth and young adult (12-25) respondents who were: (1) are at risk of initiating tobacco use; (2) have experimented with tobacco (do not use or experiment with combustibles); or (3) have experimented with multiple tobacco products. To achieve the number of participants, we anticipated needing to screen 4,050 respondents.

Under the approved Gen IC, respondents are to be recruited through an online self-administered survey through a web-based panel. The data collection under the approved Gen IC is intended to measure youth and adult perceptions of and reactions to various tobacco-related facts and messages to learn about opinions of tobacco product education messaging, tobacco-related facts and tobacco related knowledge, attitudes, and beliefs (KABs).

Updates Made to Study Materials and Relevant Documents associated with the previously approved Gen IC to Account for Four Studies

The four unapproved studies (described in subsequent sections in the memo) have study aims and protocols that are similar to the approved Gen IC. We are submitting relevant documents and an OMB justification memo for each of the four unapproved studies. The submitted documents in the current memo contain all study materials and the study protocols for all unapproved studies.

The total amount of burden in the four unapproved studies (Study 1: 596 hours; Study 2: 281 hours; Study 3: 453 hours; Study 4: 308 hours) did not exceed the 3,511 approved burden hours for the approved Gen IC (See Tables 1-4).

Study 1: “Hispanic/Latino Youth and Young Adult Tobacco Use Focus Group Study”

This focus group research was conducted to better develop for Hispanic/Latino youth (13-17) and young adult (18-24) populations by investigating among Hispanic youth, which are at most risk for tobacco youth and the demographic, psychographic, and sociocultural determinants of tobacco and e-cigarette use. Researchers conducted online focus groups by age cohort (13-14, 15-17, 18-24), product susceptibility and use, and level of acculturation (low, bicultural, and high). The moderator’s guide sought to gain insights on imitation of ENDS (Electronic Nicotine Delivery Systems) use and the sociocultural factors that influence the initiation as well as the sources and communication that Hispanic youth and young adults trust for health information. See Appendix A for the study materials, study protocol, and IRB approval document for Study 1.

Table 1. Estimated Annual Reporting Burden for Study 1

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth/Young Adults	Screening completion/Assent/Pre Focus Activities	1780	1	1780	0.125 (7.5minutes)	223
Parent/Guardian	Consent	1780	1	1780	0.125 (7.5minutes)	223
Participants	Focus Group	95	1	95	1.6 (95 minutes)	150
Total Annualized Hours						596

Study 2: Developing Strategic Concepts Designed to Prevent Multicultural Youth Tobacco Use

These focus groups were conducted to assess youth evaluations and perceptions of strategic concepts for a potential tobacco prevention campaign tailored for Multicultural youth (13-17). This study consists of focus groups made up of cigar, little cigar, and cigarillo susceptible youth and experimenters. Focus groups were separated by susceptible non-triers and experimenters. The goal of the focus groups is to inform and refine development of campaign strategic concepts and messages to ensure that the campaign will be relevant and persuasive to youth in the target audience. Focus group activities included a check-in survey, an introduction, a general discussion about cigar products, tobacco product use and perceptions, and tobacco-related fact testing. See Appendix B for the study materials, study protocol, and IRB approval document for Study 2.

Table 2. Estimated Annual Reporting Burden for Study 2

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth/Young Adults	Screeners completion	410	1	410	0.13 (8 minutes)	55
Parent/Guardian of Invited Youth	Permission	410	1	410	0.08 (5 minutes)	34
Participants	Assent	410	1	410	0.08 (5 minutes)	34
	Focus Group/Interview	105	1	105	1.5 (90 minutes)	158
Total Annualized Hours						281

Study 3: Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS Use

This research study was designed to understand how youth (aged 13 to 17) and young adults (aged 18 to 20), who are at risk of initiating (susceptible) or who have experimented with Electronic Nicotine Delivery Systems (ENDS), react to various campaign creative concepts. Information garnered from focus groups helped inform FDA/CTP's efforts to develop and implement public health education campaigns to prevent initiation and regular use of ENDS among youth and young adults. Focus groups focused on comprehension, relevance, relatability, believability, and overall reactions to presented creative concepts. See Appendix C for the study materials, study protocol, and IRB approval document for Study 3.

Table 3. Estimated Annual Reporting Burden for Study 3

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth/Young Adults	Screener completion	362	1	362	0.08 (5 minutes)	29
Parent/Guardian of Invited Youth	Permission	362	1	362	0.08 (5 minutes)	29
Participants	Assent/Consent	362	1	362	0.08 (5 minutes)	29
	Focus Group/Interview	231	1	231	1.58 (95 minutes)	366
Total Annualized Hours						453

Study 4: Creative Concept Testing Designed to Prevent Youth and Young Adult Smoking

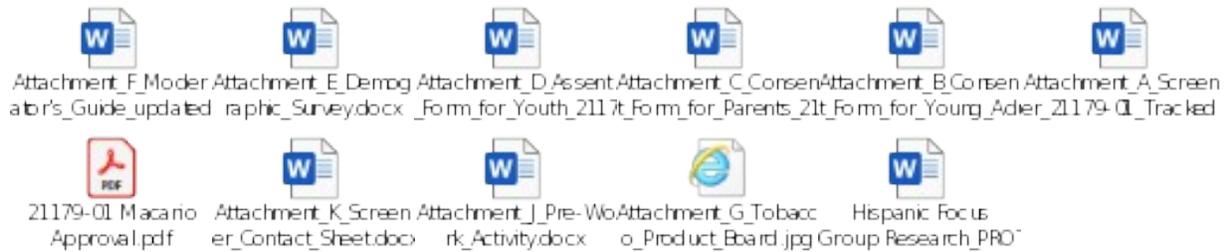
This research study was designed to understand how youth (aged 13 to 17) and young adults (aged 18 to 20), who are primarily at risk of initiating (susceptible) or who have experimented with cigarettes (experimenter), react to various campaign creative concepts. Information garnered from discussion groups informed FDA/CTP’s efforts to develop and implement public health education campaigns to prevent initiation and regular use of cigarettes and nicotine among youth and young adults. See Appendix D for the study materials, study protocol, and IRB approval document for Study 4.

Table 4. Estimated Annual Reporting Burden for Study 4

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Youth/Young Adults	Screener completion	659	1	659	0.08 (5 minutes)	55
Parent/Guardian of Invited Youth	Permission	659	1	659	0.08 (5 minutes)	55
Participants	Assent/Consent	659	1	659	0.08 (5 minutes)	55
	Focus Group/Interview	231	1	90	1.58 (95 minutes)	143
Total Annualized Hours						308

**APPENDIX A:
Study 1 Study Materials, Study Protocol, and OMB Justification Memo**

Study 1 IRB Approved Study Materials:

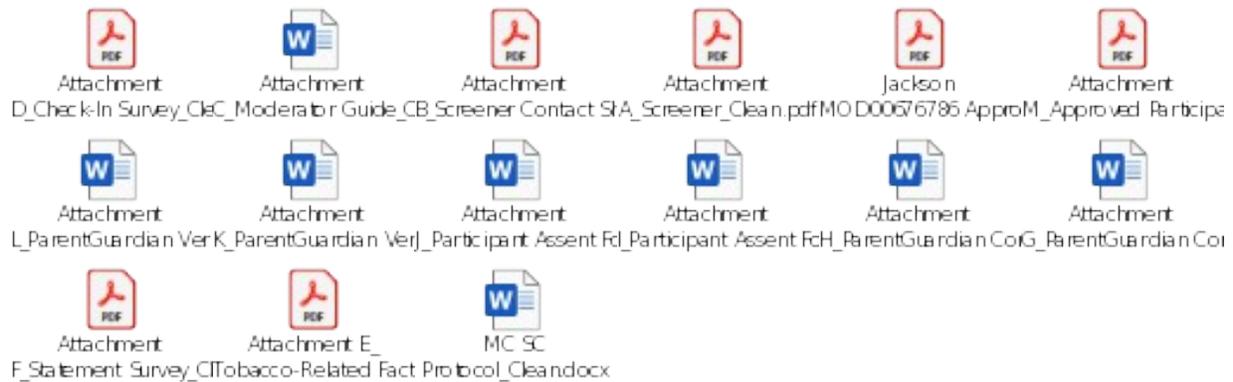


Study 1 OMB Justification Memo:



**APPENDIX B:
Study 2 Study Materials, Study Protocol, and OMB Justification Memo**

Study 2 IRB Approved Study Materials:



Study 2 OMB Justification Memo:



**APPENDIX C:
Study 3 Study Materials, Study Protocol, and OMB Justification Memo**

Study 3 IRB Approved Study Materials:



Study 3 OMB Justification Memo:



**APPENDIX D:
Study 4 Study Materials, Study Protocol, and OMB Justification Memo**

Study 4 IRB Approved Study Materials:



Study 4 OMB Justification Memo:

