FDA DOCUMENTATION FOR THE GENERAL CLEARANCE OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS (0910-0796)

TITLE OF INFORMATION COLLECTION: Developing Brand & Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (TCA) (Public Law 111-31) was signed into law. The TCA granted to the Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products; to inform the public on health-related issues; and to protect public health by reducing tobacco use and by preventing death and disease caused by tobacco use. Part of the FDA's responsibility is to inform the public on health-related issues. In order to develop the appropriate messaging to inform the public, it is important for the FDA to conduct research to gain insight into youth perceptions of tobacco prevention messaging.

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking Office of Management and Budget (OMB) approval under the generic clearance 0910-0796 to conduct focus groups with American Indian and Alaska Native (AI/AN) youth ages 13 to 17. The research will be used to inform CTP's effort to target AI/AN youth with tobacco education messaging that will effectively influence teens at risk of tobacco use.

AI/AN adults and youth have significantly higher smoking rates than any other racial or ethnic group in the country, leading to major disparities in health outcomes (CDC, 2017; Odani, Armour, Graffunder, Garrett, & Agaku, 2017). AI/AN youth tend to initiate cigarette smoking earlier than non-AI/AN youth and are more likely to currently use tobacco compared to the general population, including cigarettes, cigars, smokeless tobacco, and electronic cigarettes (CDC, 2015; RTI International, 2013; Schinke, Schilling, Gilchrist, Ashby, & Kitajima, 1989).

These trends may be in part explained by the fact that tobacco has a long-ingrained influence in many of these communities, some of which are unique to AI and AN cultures (RTI International, 2013; Hodge, 2001). Yet, AI/AN youth receptivity to tailored tobacco messaging approaches are less known. The disproportional ways in which tobacco use affects the AI/AN population can be addressed through a culturally tailored and targeted public health education campaign.

2. **Intended use of information:**

The information obtained through this study will inform the development of FDA's AI/AN youth tobacco education campaign. The list below illustrates a range of some of the purposes and uses for the proposed information collection; other uses may emerge after the collection as well:

- Refine creative concepts to be developed into video ads for FDA's AI/AN campaign.
- Help inform FDA and other stakeholders on the potential impact of campaign messaging tailored for a specific population.
- Help to inform future programs that may be in line with the strategic priorities of the current campaign.

Specifically, focus group participants will answer questions regarding comprehension, relevance, and impact of several brand and creative concepts. Results will be used to refine future campaign materials and messaging.

3. **Description of respondents:**

The study will consist of up to 12 focus groups, each with up to 16 youth ages 13 to 17 who self-report as American Indian and/or Alaska Native and indicate that they or a parent/caregiver are a member of a tribe or village. Focus groups will be held with youth who are 1) experimental cigarette users (i.e., have smoked at least one puff of a cigarette but no more than 99 cigarettes in their lifetime) or 2) current non-cigarette users who are susceptible to future cigarette use (i.e., think they might try to smoke a cigarette in the near future or would try if a friend offered it to them). Focus groups will be separated by cigarette user status. Age will also be considered in the formation of focus groups such that participants closer in age will be prioritized for the same group.

Participants will be enrolled via community-intercept recruitment across the US. The screening criteria are based on age, cigarette use status, intention to use cigarettes in the future, self-reported race/ethnicity, and AI/AN tribal affiliation will be gathered during the screening process (see Screener).

All potential participants will complete a Screener survey to determine their qualification for inclusion into the discussion groups. The Screener will be administered either in-person, as a paper survey, or as an electronic survey sent via text or email by a recruiter. Electronic screening is designed to lower the potential burden and increase efficiency of community-intercept recruitment by allowing for remote screening of interested youth. Specific avenues for ensuring access to youth will vary by location and will be determined through collaboration with community contacts. For example, recruiters may access youth through community centers, tribal health programs, after-school programs, at centrally located shopping centers where youth and families gather, through parent/guardians, or at community events and gatherings (i.e., festivals, sports tournaments, etc.). Recruiters will sample as many individuals, as well as entire groups, as possible to better ensure a diversity of ages and genders. Researchers will never turn away individuals who ask to fill out a Screener. Potential participants will be informed that any information they provide will be private and not shared with their parents or anyone outside of the research team.

All enrolled participants will be asked to answer questions about their tobacco-related behaviors, cultural engagement/values, and reactions to tailored campaign brands and

creative concepts, in addition to demographic information which will be collected during the screening process.

4. **Date(s) to be conducted and location(s):**
The study is projected to occur between September 1, 2019 and September 1, 2020. The focus groups will be conducted in geographically diverse locations throughout the U.S.

5. **How the information is being collected:**
The information will be collected through up to 12, 90-minute in-person focus groups led by a professional moderator with experience leading focus groups with youth. The study will consist of a mix of activities, including individual surveys and qualitative discussion to solicit youth reactions to campaign brand materials (i.e., brand names, logos, and taglines) and up to six creative concepts per focus group (see Moderator Guide). The moderator will encourage participants to respond openly and spontaneously. Data will be collected at convenient locations, such as professional meeting rooms or focus group facilities in the evenings or on weekends and will be livestreamed and audio recorded when possible. If a participant does not provide verbal permission for audio recording, the group will not be recorded and instead notes will be taken. The focus groups will be observed by FDA and campaign contractor staff.

Upon checking in with research staff for the focus group, participants will complete the Check-In Survey, which will assess participants' tobacco-related behaviors and cultural engagement/values (see Check-In Survey). The survey should take no longer than seven minutes to complete. Following the Check-In Survey, the moderator will provide a three-minute Study Introduction, including general instructions for participation in the focus group.

Next, participants will engage in a campaign brand testing discussion and will fill out the Brand Test Survey to assess reactions to potential campaign brand names, logo designs, and brand taglines (see Brand Test Survey Versions A & B). Participants will be prompted to answer sets of survey questions about their favorite brand names and logos in the survey, followed by a discussion about taglines. The order of items on the Brand Test Survey will be randomized in two versions to reduce order effects, thus participants will either see Version A or Version B.

The remaining 55 minutes of the focus group will consist of a stimulus-driven discussion. Each focus group will view up to six concepts, each lasting approximately 30-60 seconds. See the Creative Addendum for examples. After viewing each creative concept, participants will individually complete a short Creative Concept Survey to assess their initial reactions to that concept, followed by group discussion. Six preliminary creative concepts will be tested across focus groups. Viewing order will be rotated to minimize order effects across groups.

During the discussion, the moderator will guide participants with a series of questions designed to assess their initial reactions to each creative concept, including message

comprehension, message perceptions (e.g., relatability, innovativeness), and general ad receptivity. Additionally, questions will be asked on the concept's effectiveness to influence attitudes and behavior about cigarettes, the credibility of the message, and the actions youth might take in response to the concept (e.g., sharing the concept, mentioning it to a friend). These questions are used to assess the target audience's comprehension, evaluations, and perceptions of the creative concepts viewed.

6. **Confidentiality of respondents:**

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law.

Youth will receive an Information Packet which includes the Participant Assent Form and either a Parent/Guardian Opt-Out Form or a Parent/Guardian Permission Form for their parent(s)/guardian(s) to review prior to participating. Eligible youth will follow a parental opt-out procedure where, at any time prior to the start of the focus group, a parent must contact researchers if they do not want their child to participate. In instances where parent/guardian permission is requested, the parents/guardians of youth invited to participate in a focus group will complete a permission form prior to their child's participation., the parents/guardians of youth invited to participate in a focus group will complete a permission form prior to their child's participation. For youth who do not return a signed permission form but still wish to participate in the focus group, researchers will attempt to obtain verbal parental permission using the Verbal Parental Permission Script.

All qualified youth will be informed that they will either need to bring their signed Participant Assent Form with them on the day of the focus group, or that they will be able to read and sign the Form upon arrival to the focus group. The assent form will contain a statement that no one will be able to link the respondent's identity to his/her responses.

Prior to focus group start, research staff will collect the signed Participant Assent Form from potential participants and will verify their signature. Only qualified youth whose parents have not opted them out or have provided permission, and who have signed the Participant Assent Form, will be allowed to participate in the focus groups. Participants will be asked for assent to audio record and livestream the focus group. In the event assent is not given to audio record, the contractor will refrain from audiotaping the session, although live notes may still be taken. If a participant verbally states that they do not want to be livestreamed, the participant will be dismissed and still receive a token of appreciation.

The Screener and focus group surveys (i.e., Check-In Survey, Brand Test Survey, and Creative Concepts Survey) are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

Neither independent contractors nor focus group agencies will share personal information regarding participants with any third party without the participant's permission, unless it is required by law to protect their rights or to comply with judicial proceedings, a court

order, or other legal process. Identifying information will not be included in the reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data will contain identifying information.

7. **Amount and justification for any proposed incentive:**

In the current study, the token of appreciation for participation is $25 for youth participants and $25 for each adult (parent or guardian) who drives youth to the focus group as a thank you for the participant and their parent/guardian's time. The token of appreciation will be distributed directly to the participant and directly to each adult, separately, at the conclusion of the focus group or when the participant leaves the group, whichever is earlier. If a participant is removed from the focus group for any reason, he/she will still receive the token of appreciation.

The target audience for the current data collection, AI/AN youth ages 13-17 who are at-risk for tobacco use, represents a highly specific population which is more difficult to recruit than a general population audience, increasing the need for a token of appreciation to recruit and retain participants. The study is taking place in situations where travel is challenging and/or time consuming, and the participants (particularly adolescents aged 13-17) have limited access to transportation. In order to take part in this research, we are asking participants to secure transportation to the focus group and maintain a high-level of engagement during focus groups, providing survey responses and thought-intensive, open-ended feedback on creative concepts for potential campaign development. Providing a token of appreciation shows respect by recognizing and acknowledging the time burden placed on participants and takes into consideration the particular challenges this target audience may face in reaching the focus group location. The token of appreciation is similar to that which is offered for other studies of this type.

Numerous empirical studies have shown that a token of appreciation can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002). The use of a modest token of appreciation is expected to enhance focus group participation rates without being an inducement for participation. A token of appreciation must be high enough to address competing demands for participants' time and to equalize the burden placed on participants with respect to their time and cost of participation. An inadequate token of appreciation may also result in a significantly more difficult and lengthy recruitment process and/or increases in the number of participants who agree to participate and then do not show up or drop out early. We also believe that the token of appreciation will result in higher data validity as participants will be more likely to attend and engage in the focus group activities.

A token of appreciation is necessary to ensure adequate participation among harder-to-recruit populations such as youth, lower income socio-economic groups, racial and ethnic minorities, and high-risk populations. Research participation and retention has been shown to be lower among socially disadvantaged and racial/ethnic minority multicultural

populations (Patel, Doku, & Tennakoon, 2003; Giuliano et al., 2000). Studies have linked low participation among AI/AN populations to a general mistrust of institutions, stemming from historical instances of unethical and/or culturally insensitive research practices (Noe et al., 2006; Stoddart et al., 2000). Factors that may lower at-risk youth engagement and retention in research and prevention programs include financial and neighborhood stress, low social support, instability at home, and mistrust of research programs (Hooven, Walsh, Willgerodt, & Salazar, 2011; Zand et al., 2006; Post, Gilljam, Bremberg, & Galanti, 2012). However, a monetary token of appreciation has been demonstrated to be an effective means of recruiting and retaining at-risk and multicultural participants (Martinson et al., 2000; Booker, Harding, & Benzeval, 2011; Caldwell, Hamilton, Tan, & Craig, 2010; Walter, Burke, & Davis, 2013). Relevant to the current collection, studies with AI/AN participants have demonstrated that a good faith gesture of a monetary token of appreciation can increase participation rates in research studies, including focus groups (NCAI Policy Research Center, 2016; Noe et al., 2006; Buchwald et al., 2006; Kaufman et al., 2014; Norton & Manson, 1996).

In previous studies that the Office of Health Communication and Education (OHCE) has conducted with similar groups of youth (e.g., AI/AN youth and participants either susceptible to or having experimented with tobacco products) using similar protocols (e.g., 90-minute in-person focus groups), OHCE has used a $50 token of appreciation ($25 for each youth participant, and where applicable an additional $25 for a parent/guardian who transports one or more participants to the focus group). With this token of appreciation OHCE was successfully able to recruit and complete the focus groups within the relatively tight schedule for focus group research (e.g., 4 geographic locations in 7 weeks or similar).

Most recently, OHCE successfully used this token of appreciation structure for 90-minute focus groups with similar AI/AN youth audiences with the study titled, Developing Strategic Concepts Designed to Prevent AI/AN Youth Tobacco Use (OMB 0910-0497). Additional studies that OHCE has successfully used a token of appreciation for 90 minute focus groups with youth audiences are as follows: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use (OMB 0910-0674); Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Reduce Tobacco Use among General Market Youth (OMB 0910-0674).

While we will take non-monetary steps to increase participation of the target audience such as reminding to screener-qualified youth, evidence indicates that a token of appreciation for participation is also necessary. As such, we believe that the current study requires the use of a token of appreciation for participants in order to overcome potential recruitment difficulties for this special at-risk population of AI/AN youth, and to promote participation and efficient data collection from the target audience for FDA's future AI/AN focused campaign effort.

8. **Questions of a Sensitive Nature:**

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in

order to assess tobacco use. These questions are essential to the objectives of this information collection. Questions about messages concerning tobacco use behavior and some demographic information, such as race/ethnicity, could be considered sensitive, but not highly sensitive. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise youth that these topics will be covered during the study. In addition, this study includes the following procedures and methodological characteristics that will minimize potential negative reactions to these types of questions:

Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer, and that they may leave the focus group at any time without penalty. Raw data from data collections that include sensitive information (e.g., screening questionnaires and audiotapes) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

Participants will be provided with an email address and phone number for the Principal Investigator and the IRB should they have any questions or concerns about the study or their rights as a study participant.

9. **Description of statistical methods:**

This research relies on qualitative methods to collect data. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters. The sample drawn here is designed primarily to provide information on AI/AN youth's reactions to future campaign materials and messaging.

The campaign contractor, Rescue, has conducted rigorous internal review of the survey instruments. Trained researchers reviewed the Screener and focus group survey to verify that all questions are worded correctly. Researchers who will be involved in recruitment and data collection will be trained on administration of the instruments to ensure efficiencies in data collection. Moderators will be provided training on the content of the creative concepts and moderator guide to ensure they are equipped to facilitate constructive discussions that address the goals of the research.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Screened Youth	Screener completion	576	1	576	0.083 (5 minutes)	48
Parents of Invited Youth	Parental permission or opt-out process	192	1	192	0.083 (5 minutes)	16
Participants	Youth Assent	192	1	192	0.083 (5 minutes)	16
	Focus Group		1	192	1.5 (90 minutes)	288
Total Annualized Hours						**368**

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