

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

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

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

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 0910-0497 to conduct focus groups with American Indian and Alaska Native (AI/AN) youth ages 12 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, 2015a; RTI International, 2013; Schinke, Schilling, Gilchrist, Ashby, & Kitajima, 1989). Among AI/AN youth, current use of cigarettes and smokeless tobacco has been shown to be higher in rural areas, whereas current cigar use has been shown to be more common in densely populated areas (NSDUH, 2011; RTI International, 2013). Ever-use of cigarettes among AI/AN youth has been shown to be particularly high in the Northern Plains, Alaska, and the Southwest, with prevalence estimates ranging from 65% to 71%. Evidence suggests that current use of smokeless tobacco is significantly higher among AI/AN youth compared to non-AI/AN youth in Alaska, Northern Plains, Oklahoma/Kansas, and Southeast regions (CDC, 2015b; RTI International, 2015).

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 culture (RTI International, 2013; Hodge, 2001). Yet, the role of peer influence and personal values on tobacco use intentions among AI/AN youth are less known. Additionally, AI/AN youth receptivity to tobacco messaging approaches is an area that has not been explicitly explored in the existing literature.

The disproportional ways in which tobacco use affects the AI/AN population demands our prompt attention and should be addressed through a culturally tailored and targeted public health education campaign. On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) (Public Law 111-31) into law. The FSPTCA granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect

the public health generally and to reduce tobacco use by minors. 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.

2. Intended use of information:

This information obtained through this study will inform the development of a tobacco prevention educational campaign targeting AI/AN youth. While not exhaustive, the list below illustrates a range of purposes and uses for this proposed information collection:

- Gain and understanding of AI/AN youth's culture and relationship with tobacco products
- Identify the most promising strategic concepts to inform further creative development
- Inform further programs that may be designed for similar purposes.

3. Description of respondents:

The study will consist of up to 14 focus groups, each with up to 12 American Indian and Alaska Native youth ages 12 to 17. Focus groups will primarily be held with youth who are experimental tobacco users (i.e., experimenters) or current non-tobacco users who are susceptible to future tobacco use (i.e., susceptible non-triers). Focus groups with current non-daily users may be formed based on observed prevalence. Groups will be segmented based on age (12 to 13 year olds and 14 to 17 year olds) and by tobacco user status (i.e., experimenter, susceptible non-trier, or current non-daily user).

Participants will be enrolled via in-person recruitment across the US. The screening criteria are based on age, tobacco use status, intention to use tobacco in the future, self-reported race/ethnicity, and AI/AN tribal affiliation.

All potential participants will complete a Screener to determine their qualification for inclusion into the focus groups. The Screener survey will be administered as a paper survey by an onsite recruiter. Specific avenues for ensuring access to youth will vary by location and will be determined through collaboration with community contacts. For example, recruiters may be stationed in convenient locations that community contacts will direct youth to, including community centers, tribal health programs, after-school programs, at centrally located shopping centers where youth and families gather, 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 knowledge, attitudes, and beliefs, and psychographics, 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 August 15, 2018 and January 31 2019.

5. How the Information is being collected:

The information will be collected through up to fourteen, 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 quantitative assessments (individual surveys), photo-based activities (picture sorting and moderator-assisted interview questions), and qualitative discussion to solicit youth reactions to up to six video stimuli per focus group.

Following recruitment, researchers will review completed Screeners and identify eligible youth. Up to twelve eligible youth will be selected for invitation to attend each focus group. The focus group will be held up to two weeks after recruitment to allow for appropriate coordination and notice to participants/parents. Eligible youth who are invited to participate in a focus group will be notified via text message and/or phone call via the contact information that they provide. Eligible youth will be provided a Parent/Guardian Permission Form. The Parent/Guardian Permission and Opt-Out information are combined into one form for ease of communication and use by parents and community contacts, who are key conduits. Eligible youth ages 14-17 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, and eligible youth age 12-13 must return a signed Parent/Guardian Permission Form to participate in the study. Researchers will attempt to obtain verbal parental permission using the Verbal Parental Permission Script for youth age 12-13 who do not return a signed permission form but still wish to participate in the focus group. All youth regardless of age will complete the Participant Assent Form before beginning the focus group. Youth must complete the Participant Assent Form and have obtained written/verbal parental permission or have not been opted-out by their parents in order to participate in the focus groups; youth who do not meet these criteria will not be able to participate in the focus groups.

Focus groups will be conducted in the evenings or on weekends at a convenient location within the community, including commercial focus group facilities. Separate focus groups will be conducted with 12 to 13 year-olds and 14 to 17 year-olds. The moderator or focus group assistant will utilize the Moderator Guide and obtain verbal confirmation from all participants to audio record the focus group. If a participant does not provide verbal permission for audio recording, the group will not be recorded and instead the focus group assistants will take notes.

After the study introduction, participants will begin individual activities, which differ slightly by age group. For 14-17 year olds, focus group staff will assign half of the participants to begin the Individual Picture Sort. In the Individual Picture Sort, participants will sort photos of unknown youth into two to ten groups according to social groups they observe in their school and community. The facilitator will interview the participant about the groupings and record responses. The other half of the participants will complete the Check-In Survey, which will assess participants'

tobacco-related knowledge, attitudes, and beliefs, and psychographics. After completing the first assigned activity, participants will be instructed to switch to the activity they have not completed yet. Following these activities, there will be a brief group discussion activity (Rapid ID Projection), which lasts five minutes. Participants will be shown a slide with numbered pictures of unknown youth and will be asked questions about their perceived habits and interests. In total, the first part of the focus group will take forty-five minutes.

For 12-13 year olds, the Individual Picture Sort will not be conducted and all participants will complete Check-In Survey simultaneously, taking fifteen minutes. This group will engage in a longer ID Projection activity in which additional behavioral risk questions will be asked about the pictures, lasting up to twenty-five minutes. In total, the first part of the focus group for 12-13 year olds will take forty-five minutes.

For both age groups, the remaining forty-five minutes of the focus group will consist of a stimulus-driven discussion. Up to fifteen Video Stimuli will be tested in this study. Each focus group, however, will only view up to six of the videos, each lasting approximately 30-45 seconds. Each video will be revealed one at a time, and respondents will be asked their opinions on each video before viewing the next one. To collect views on all videos, the selection of videos and the order in which they are shown will be rotated across focus groups. In addition, five alternate videos will be available in the case that saturation is reached.

During the discussion, the moderator will guide participants with a series of questions designed to assess their initial reactions to the strategic concept, including what they liked or disliked, how the ad made them feel, and overall comprehension of the ad. Additionally, questions will be asked on whether the ad influenced the participant's thoughts about tobacco, the degree to which the claims in the ad were believable, and the actions they might take in response to the ad (e.g., sharing the ad, mentioning it to a friend). These questions are used to assess the target audience's comprehension, evaluations, and perceptions of the strategic concepts viewed.

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

Prior to focus group facilitation, youth focus group participants will be asked by research staff to complete an assent form. At the beginning of the focus group, a facilitator will review the content of the assent form. The assent form will contain a statement that no one will be able to link the respondent's identity to his/her responses. Additionally, focus group questions will not ask participants to provide identifying information as part of their 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.

6. Number of focus groups:

Up to fourteen focus groups will be conducted.

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 12-17 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 near Indian reservations and Native villages that are remote, where travel is challenging or time consuming, and the participants (particularly adolescents aged 12-17) 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 provide both survey responses and thought-intensive, open-ended feedback on strategic concepts for potential campaign development that require a high level of engagement. 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 (Hoooven, 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). 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., 2016; 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., 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 \$50.00 token of appreciation (\$25.00 for each youth participant, and where applicable an additional \$25.00 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 4 weeks or similar).

The previous 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); Wave 3 Phase 1 Qualitative Research: General Market (“The Real Cost”) At-Risk Youth Tobacco Prevention Focus Groups (OMB 0910-0674).

While we will take non-monetary steps to increase participation of the target audience such as the delivery of reminders 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.

The Screener and Check-In Survey are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

Participants will be informed that the focus group will be audio recorded and they will have an opportunity to provide or reject permission for the group to be recorded at the start of the focus group.

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 (I.E., Sample Size & Method of Selection):

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 perception on tobacco use and youth culture.

The campaign contractor Rescue has conducted rigorous internal review of the survey instruments. Trained researchers reviewed the Screener and Check-In Surveys 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 strategic 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	504	1	504	0.083	42
Parents of Invited Youth	Parental permission or opt-out process	168	1	168	0.083	14
Participants	Youth Assent	168	1	168	0.083	14
	Focus Group (Study Introduction, 5 minutes; Check-in Survey, 15 minutes; Individual Picture Sort, 20 minutes (14-17 yr olds only); Rapid ID Projection / ID Projection, 5 minutes for 14-17 yr olds and 25 minutes for 12-13 yr olds; Stimulus-Driven Discussion, 45)	168	1	168	1.5	252
Total Annualized Hours						322

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FDA CENTER: Center for Tobacco Products (FDA, CTP)

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