

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE
OF TESTING COMMUNICATIONS ON TOBACCO PRODUCTS
(0910-0796)**

TITLE OF INFORMATION COLLECTION: American Indian/Alaska Native Campaign: Focus Group Study of Reactions to Strategic Concepts Designed to Prevent Youth Tobacco Use; OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration’s (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0796 to conduct focus groups with American Indian/Alaska Native (AI/AN) youth aged 10–16 (n=140) and AI/AN adults, parents, and community leaders (n=80) in five AI/AN communities in Alaska and South Dakota and Minnesota in the Northern Plains region. The research will be used to assess advertising concepts designed to reduce AI/AN youth tobacco use.

The AI/AN population faces great disparities, with high rates of tobacco use and smoking-related outcomes. The AI/AN population has significantly higher smoking rates than any other racial or ethnic group in the country,ⁱ with the highest percentage of current users in Alaska (40%) and the Northern Plains (44%).ⁱⁱ Cancer and heart disease are the two leading causes of death among AI/AN people,ⁱⁱⁱ and cigarette smoking is a major risk factor for both.^{iv}

2. Intended use of information:

Information obtained through this study will provide insights to inform the development of a public education campaign aimed at preventing and reducing tobacco use among AI/AN youth. This study will use a community-based participatory research (CBPR) approach to (1) inform campaign development on the target population in terms of age, cultural identity, and community participation; (2) inform message development by describing youth’s perception of tobacco use, access, and initiation among AI/AN youth in their community, including relevant knowledge, attitudes, and beliefs; (3) identify influencers and how they impact tobacco use behaviors among AI/AN youth; and (4) identify appropriate traditional, digital (social media, etc.), and community engagement channels to reach AI/AN at-risk youth.

3. Description of respondents:

The study will consist of twenty-two (22) focus groups, with a total sample of up to 220 AI/AN youth and adults. Each group will be comprised of approximately 8-10 participants, and groups will be segmented by youth age (10-12 year olds grouped together, 13-16 year olds grouped together) and adult influencer status (parents and caregivers will be grouped together, elders/tribal leaders/service providers will be grouped together). Information on youth age and adult influencer status will be collected during the screening process. Due to the qualitative nature of this research, the sample size is projected to provide an appropriate amount of data to reach thematic saturation regarding the content of the concepts. Purposeful sampling will be used to invite as broad a group of participants as possible within the target group.

4. Date(s) to be conducted:

The study is projected to occur between May 1, 2016 and April 30, 2017.

5. How the information is being collected:

The information will be collected through twenty-two (22) in-person focus groups, adult and youth focus groups being led Native professional moderators (and youth focus groups being co-led by local youth co-facilitators). Participants will provide assent/consent prior to focus groups (5 minutes). Each group will be asked a series of questions using a semi-structured discussion guide to encourage participants to inform: a definition of the beneficiary and target population; message content around youth's perception of tobacco initiation, use, and access; influences and how they impact use behaviors; and appropriate media channels to reach AI/AN at-risk youth. Discussions will be followed by a world café exercise, which will collect participant responses to strategic concepts. If all participants provide assent/consent before discussion begins, responses will be audio recorded and transcribed. The focus groups will take place in a community location, such as a school or community center, and will be in a private area.

Focus Groups (60 minutes): Youth focus group sessions will begin with an icebreaker activity followed by 50 minutes of discussion and a 5-minute restroom/transition break. After the brief break participants will experience a 25 minute interactive activity (see world café description below), followed by a 10-minute snack break, and then return to group for a 25-minute theme validation exercise to ensure note-takers accurately captured youth's contributions, followed by a brief closing. Adult focus group sessions will feature all of these same activities with the exception of the icebreaker activity. For youth ages 10–12, we will provide table toys, including pipe cleaners, Popsicle sticks, stickers, markers, play dough, and post-it notes, which have been demonstrated to be helpful to children ages 7–11.^v Focus group questions will ask youth and adults about the patterns and habits of people who smoke cigarettes and where cigarette smoking occurs in their community. The questions will address media access, preferences about social media use, including specific tools and preferences, and the consumption of media sources. Focus group questions will also probe what kinds of health information AI/AN youth and adults seek online or through social media sources, and who they trust for health messages.

Reactions to Strategic Concepts: World Café and Theme Validation (60 minutes): An interactive activity, the world café, will follow the focus group discussion. The world café will consist of three tables equipped with butcher paper and colored markers. Focus group participants will be broken into dyads or triads depending on the total number of participants, and will rotate through the three tables, spending about six minutes at each table to review and discuss the stimuli/message platform, reacting and discussing the ideas captured on paper from the previous group, while writing down additional ideas or drawing pictures that describe their reaction to the concept.

There will be a total of four concepts that will be discussed during the world café activity (across all focus group held), but each focus group will only review three out of the four concepts due to time constraints. Each subsequent focus group will rotate through a set of three concepts that includes the concept that was not reviewed in the preceding focus group.

For example, the first focus group will review the first, second, and third concepts. The second group will review the second, third, and fourth concepts. The third group will review the third, fourth, and first concepts, and so on, until all 22 focus groups are completed.

The 25-minute world café exercise will be followed by a 10-minute snack break and a 25-minute theme validation and closing. Finally, the moderator will conclude the focus group and assist participants with collecting their incentives and checking out of the focus group.

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.

Prior to focus group facilitation, adult and youth focus group participants will be asked by research staff to complete a consent/assent form. At the beginning of the focus group, the facilitator will review the content of the consent/assent form. The consent/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.

Before each group begins, the moderator will obtain verbal consent/assent from the participants to audio record the session. In the event consent is not given, the contractor will refrain from audio recording the session, although live notes/transcriptions may still be taken. The consent form will also contain a statement notifying participants that audio recording will occur.

Community Liaisons and Youth Co-Facilitators will be selected from each community, and will be involved in the recruitment of adult and youth focus group participants. Community Liaisons are locally integrated adult community leaders who will assist with focus group planning and recruitment. They are employees of research organizations, including tribal governments, Native non-profit organizations, tribal colleges, or Native health corporations. The Community Liaison will recruit adult participants, work with NICWA to secure and manage site logistics and scheduling, and be involved with participant communication. Community Youth Co-facilitators will be in the upper age range of focus group youth participants; they will recruit youth and adult participants and co-lead the youth focus groups with a professional facilitator.

Youth Co-facilitators will be trained in the importance of confidentiality as part of their human subjects training, and instructed not to reveal information discussed in the focus groups outside that setting. Service providers will be reminded of the importance of not disclosing sensitive information about their youth or adult clients in the community. Data collection will be in the form of audio recording, notes taken by the note-takers, and the co-facilitator's synthesis of key points on a flip chart. While transcripts, notes (typed and handwritten) and drawings, and reports will include ideas and comments from participants, they will be stripped of identifying information.

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:

Most of the study is taking place on Indian reservations and native lands that are remote, where travel is challenging, and the participants (particularly the children aged 10-16) have limited access to transportation. It is our tribal research partner's experience that travel incentives work well with AI/AN populations as it takes into consideration the particular challenges participants may face in reaching the focus group location.

Incentives in the form of Visa gift cards will be given to focus group participants. Adults will receive one \$75 Visa gift card while there will be two gift cards for youth: one \$50 card for their participation and one \$25 card for the relevant responsible adult providing their transport to the focus group. This amount accounts for the participant's involvement in recruitment conversations, travel time, and participation in the focus group conversation, including review/validation of focus group findings as the final section of the focus group agenda. Incentives will be provided at the conclusion of the two-hour focus group; participants will each sign to acknowledge receipt. In addition, individuals who provide transportation for adult participants, whether or not they are participants themselves, will be provided with a \$25 Visa gift card (limit one transportation incentive per individual regardless of the number of participants they transport); other transportation may be provided as needed depending on community resources and services. Refreshments will also be provided for all focus group participants.

Incentives are necessary to ensure adequate representation among harder-to-recruit populations such as youth, lower income socio-economic groups, and high-risk populations (current or former tobacco users and those susceptible to tobacco use).^{vi} In the context of this study, the target population is considered a harder-to-recruit population on multiple accounts (youth aged 10–16 who, because of high prevalence rates in their community, are also at risk of or are currently experimenting with tobacco use). The study also requires youth and adult respondents to comment on an activity that is a sensitive subject and could cause them to be reluctant to participate. Two additional logistical challenges merit consideration in determining incentive amounts. The population of several of the sites is fairly small; incentives will be key in attracting a sufficient number of representative participants. Depending on the time of year, transportation may also be challenging and expensive. Whether sub-zero temperatures facilitate driving on the frozen Yukon-Kuskokwim River in Bethel or taking a snow machine from a village within Association of Village Council Presidents (Bethel) region, the target population at these sites may just as readily travel by boat or snow machine as by car or bus. On the Rosebud Reservation, participants may have to travel an hour or more over rural roads or through winter conditions. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth respondents.

8. Questions of a sensitive nature:

The questions do not concern personal tobacco use or personal health, but are strictly limited to observations of peer behavior, media access, and habits regarding media and social media use. Focus group participants (both youth and adults) will, as co-researchers in this community-based participatory research design, help inform and shape empowering, culturally- and community-focused messages aimed at preventing and reducing tobacco use among AI/AN youth. Asking participants about tobacco use or experimentation as a screening question (or focus group question) presents potential harm, as tobacco use is illegal for youth. As a sensitive topic, youth may feel alienated and unwilling to be honest in focus group discussions. Excluding AI/AN youth per their tobacco use or experimentation is culturally inappropriate. This is especially an issue in small AI/AN communities where being excluded from research has resulted in mistrust historically, and is counter to tribal values of inclusion, equity, and mutual benefit among community participants.^{vii}

Any data that are reported will be de-identified, and results will not be reported for subgroups where low sample numbers may make it possible to identify individuals.

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.

Community Liaisons and Local Community Youth Co-facilitators will assist in the recruitment and facilitation of focus groups with their respective community members using a CBPR approach to recruitment.^{viii} The research team will work with the local Community Liaison and the Youth Co-facilitator to use a variety of community-based approaches to recruitment, the most important in AI/AN communities being word of mouth. Word of mouth recruitment includes flyers in local media, local community partners contacting their friends, work and schoolmates, local parent committees, coaches, clubs, service groups, clinics, local stores, and community centers. Community Liaisons and Youth Co-facilitators will use natural gathering places and/or social relationships to inform people about the opportunity to participate in a focus group and share their ideas.

In order to participate in the focus groups, participants must be fluent in English; self-identify as a) an AI/AN youth ages 10–16, b) a parent or caregiver of an AI/AN youth, or c) an influential adult (e.g., elder, tribal leader, or service provider) who self-identifies as being engaged in the communities in which we are conducting focus groups. Individuals who do not meet the aforementioned criteria will be excluded from participation. Efforts will be made during recruitment to have a balanced sample of males and females in the groups.

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

Respondent and Participation Type	No. of Respondents	Max Participation Time (Minutes)	Burden (Hours)
Screened Potential Participants			
Screener	440	5	37
Adult Consent	80	5	7
Parental Consent	140	5	12
Youth Assent	140	5	12
Total Screened	440		68
Focus Group Participants			
Youth	140	120	280
Adults	80	120	160
Total¹	220		440
Total Burden			508

¹ The total number of respondents is 440 (adult and youth); one-half of those (220) represent the total number of participants in this study.

REQUESTED APPROVAL DATE: April 29, 2016

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FDA CENTER: **Center for Tobacco Products (FDA/CTP)**

- ⁱ CDC (2014) Cigarette Smoking in the United States. Retrieved from <http://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html#populations>
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- ⁱⁱⁱ CDC (2014). American Indian and Alaska Native Populations. Retrieved from <http://www.cdc.gov/minorityhealth/populations/REMP/aian.html#10>
- ^{iv} CDC (2014). Smoking and Tobacco Use. Retrieved from http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm
- ^v Gibson, J. E. (2012). Interviews and focus groups with children: Methods that match children’s developing competencies. *Journal of Family Theory & Review*, 4. doi:10.1111/j.1756-2589.2012.00119.x
- ^{vi} Groth, S. W. (2010). Honorarium or coercion: Use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*, 41(1), 11–22.
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