

## **American Indian/Alaska Native Campaign: Focus Group Study of Reactions to Strategic Concepts Designed to Prevent Youth Tobacco Use**

### **ADULT CONSENT FORM**

**This form can be read to you if you ask.**

This form will tell you about a research study you can join. This study is being done by the National Indian Child Welfare Association (NICWA), Better World Advertising (BWA), and the Food and Drug Administration – Center for Tobacco Products. If you have questions please ask us. Take as much time as you need to decide. If you choose to be in the study, you will need to sign this form.

#### **What is the name of this research study?**

*American Indian/Alaska Native Campaign: Focus Group Study of Reactions to Strategic Concepts Designed to Prevent Youth Tobacco Use*

#### **Why is this study being done?**

The purpose of this project is to develop a public education campaign to prevent smoking among American Indian and Alaska Native youth. We need your help to inform our campaign, which will be aimed at youth in your community. Based on what we learn from you—as well as any youth in your family that may be participating—we will develop positive campaign messages and images. In the months to come, we will return to your community to share our messaging and creative ideas and ask for your feedback. Then we will make improvements based on the feedback and other ideas you share with us.

#### **What is the goal of the study?**

The goal of this study is to prevent and reduce tobacco use among American Indian and Alaska Native youth.

#### **Why am I being asked to be in the study?**

You are being asked to be in this study because you:

- Are a parent or caregiver of an American Indian/Alaska Native youth in [community] who is engaged in the community

**Or**

- Are an elder, community leader, or service provider in [community]

#### **Who should not be in the study?**

Adults who are not American Indian/Alaska Native and are not a parent or caregiver of an American Indian/Alaska Native youth in [community] or an elder, community leader, or service provider in [community]

#### **Who has reviewed and approved this study?**

This study has been approved by the Alaska Area Institutional Review Board (IRB), and Great Plains Area IRB, National Indian Health Service IRB, and the FDA. IRBs review proposed studies to make sure they follow federal regulations for the protection of human participants in research. This project has been approved by the [relevant native or tribal authority who provided approval].

**Who is funding this study?**

Money for this study is coming from the Food and Drug Administration – Center for Tobacco Products.

**If I agree to be in this study, what will I be asked to do?**

If you decide to be in this study we will ask you to do several things:

1. You will be asked to discuss a series of questions about youth tobacco use and media habits (for example, if youth use social media websites like Facebook, listen to radio programs, or watch television) in your community.
2. You will be shown some images and will have a chance to respond to some suggested campaign messages or ideas.

**Will specimens be taken or stored?**

No specimens will be taken or stored.

**How many people will be in the study?**

You will be one of an estimated 80 adults participating in this study overall. We estimate that ## adults will participate in location.

**How much of my time will this study take?**

The focus group will take two hours.

**How much time will the whole study take?**

The whole study is expected to begin in 2016 and end in 2018.

**Is there any risk or discomfort from the study?**

There is a small risk that things that are private to you could get out. We will not keep anything that shows who said what. There is also a risk that after the group is over, other group members might talk about what was said in the group. Before we start the group, everyone has to agree that they will not talk to others about who said what during the meeting. The discussion will be audio recorded and notes will be taken. The audio recordings will be transcribed, or typed up. Neither the transcriptions nor handwritten notes will contain the names of the participants—only what they said.

**What are the possible risks of this study to my community?**

Risks of a study to a community are not always known. The people involved in this study have worked closely with [relevant native or tribal authority] to make a plan to lessen the risk of harm to your community. This plan says all presentations or publications must be approved by [relevant native or tribal authority] leadership.

**How will I benefit from this study?:**

There will be no direct benefits to you, but the study will help us learn more about kids and smoking.

**Will I be paid to be in the study?**

All adult focus group participants will receive a \$75 [MasterCard or Visa] gift card. Individuals who provide transportation for participants, whether or not they are participants themselves, will be provided with a \$25 [MasterCard or Visa] gift card. There is a limit of one transportation incentive per individual regardless of the number of participants transported.

**Who will be able to see my records?**

We are not asking for medical records; we will not have access to your medical records.

**How will you protect my confidentiality?**

All information will be kept private to the extent that is legally possible. Information we collect from you will be stored with your study identification number and not your name or other information that would

identify you. Consent forms and any information collected on paper will be stored in locked cabinets and electronic data in password-protected secure computer files. Data will be kept for at least 3 years after the funding period ends. It may be kept longer, but all protections of the data must stay in place. Data will be completely destroyed when it is no longer needed.

Government staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

**What happens to the findings from the study?**

While overall results of the focus groups will not be given back to participants, at the conclusion of the focus group, the research team will review and validate the findings from that discussion group with participants. Names will not appear in any report or papers resulting from this study. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with participants and Tribal leadership. Papers will be written for publication in scientific literature. These papers will be reviewed and approved by [relevant native or tribal authority] before being published.

**Can I refuse to be in the study?**

Yes, taking part in this study is your choice. If you do decide to join the study, you can leave it at any time.

**Who do I call if I have questions later or I decide to leave the study?**

If you have any questions or study-related injuries or complaints, you may contact the Principal Investigator(s): Sarah Kastelic, PhD, MSW; skastelic@nicwa.org; (503) 222-4044 x 128

**NAME OF RESEARCHER(S) AND PHONE NUMBER(S):**

So-Investigator: Terry Cross, MSW, ACSW, LCSW; terry@nicwa.org; (503) 222-4044 x 150

If you have questions about *your rights as a study participant*, you may call the [Regional IHS IRB]:

[name, title, phone number, and e-mail of contact people]

**To be in this study, please sign your initials in the appropriate box and then sign the statement below.**

	<b><u>I agree</u></b> <i>Please initial</i>	<b><u>I disagree</u></b> <i>Please initial</i>
<b>1. CONSENT FOR FUTURE CONTACT IF APPLICABLE</b>		

I have read or been told about this research study and all of my questions have been answered to my satisfaction. I have been offered a copy of this consent. **I agree to be in the study.**

Name of participant: \_\_\_\_\_ DOB: \_\_\_ / \_\_\_ / \_\_\_

**Signature of Participant:** X \_\_\_\_\_ **Date:** \_\_\_\_\_

Study Personnel Receiving Consent: \_\_\_\_\_

<p>For non-English speaking participants only:          The participant is non-English speaking. I have translated the details of the study into the participant's Native language and have indicated their wishes in the boxes above.          Signature of Interpreter: _____          Name of Translator (please print): _____</p>
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**Paperwork Reduction Act Statement:** The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Informed Consent Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov)